Nos. 2023-2397, -2398
Volume II of III, Appx3530 to Appx4684

In the United States Court of Appeals for the Federal Circuit

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,

Appellant,

v.

OSTEOMED LLC,

Appellee.

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2022-00487 and IPR2022-00488.

CORRECTED JOINT APPENDIX

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APPENDIX INDEX

Paper/ Exhibit No.	Description	Appendix Pages
1008	U.S. Pat. Application No. 2006/0241608 et al. to Myerson et al. ("Myerson")	Appx1187
1015	Final Deposition Transcript of Karl Leinsing, MSME, PE, dated January 18, 2023 (Excerpts)	Appx1229
1016	Final Deposition Transcript of George B. Holmes, Jr., M.D., FAAOS, dated January 20, 2023 (Excerpts)	Appx1432
1021	Petition for *Inter Partes* Review of U.S. Patent No. 8,529,608 submitted by Petitioners Stryker Corporation and Wright Medical Technology, Inc. on August 30, 2021 in IPR2021-01450 (Paper 2)	Appx1664
Patent Owner's Exhibits for IPR2022-00487		
2005	Declaration of Karl R. Leinsing, MSME, PE	Appx2042
2007	Declaration of Dr. George B. Holmes, Jr., M.D., FAAOS	Appx2157
2009	Final Deposition Transcript of Michael Sherman, dated September 29, 2002	Appx2231
2016	PTAB Decision Granting Stryker's Motion to Submit Supplemental Information, IPR2021-01450 through -01453, Paper 20 (May 13, 2022)	Appx2420
2017	Declaration of Mark Sommers from IPR2021-01450	Appx2434
Docket for IPR2022-00488		
1	Petition for *Inter Partes* Review, 01/28/2022	Appx3116
6	Patent Owner's Preliminary Response, 05/16/2022	Appx3233
8	Decision Institution of *Inter Partes* Review, 08/12/2022	Appx3301
16	Patent Owner Response, 11/18/2022	Appx3356
25	Petitioner's Reply in Support of Petition, 02/17/2023	Appx3469
29	Patent Owner's Sur-Reply, 04/07/2023	Appx3530
Petitioners' Exhibits for IPR2022-00488		
1002	Declaration of Michael Sherman	Appx3646
1003	U.S. Patent No. 10,993,751 (Application No. 17/143,709) File History	Appx3793
1010	U.S. Pat. Application No. 2006/0241592 et al. to Myerson et al. ("Myerson")	Appx4017
Patent Owner's Exhibits for IPR2022-00488		
2003	Certificate of Correction for U.S. Patent No. 10,993,751	Appx4149

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC,
Patent Owner.

Case No. IPR2022-00488

U.S. Patent No. 10,993,751

PATENT OWNER'S SUR-REPLY

VI. GROUND 4: ARNOULD + ZAHIRI

A. Claim [1d]

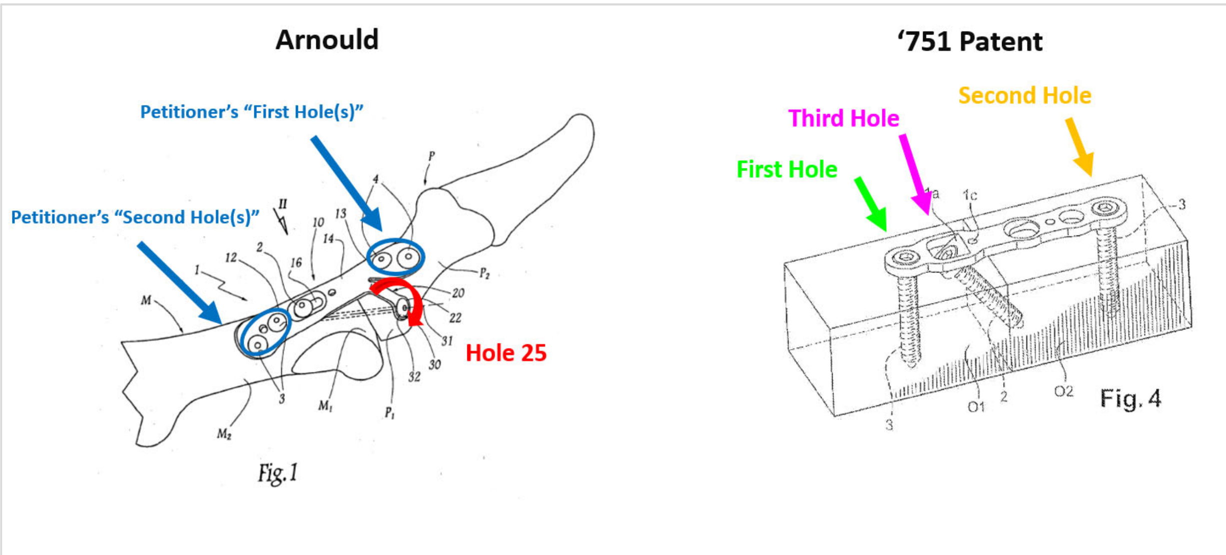
Arnould's hole 25 is not a "third hole located between said first hole and said second hole"[8] nor is it "angled relative to the longitudinal axis of said bone plate" as required by [1d]. (POR, 70-77). As discussed above in Section III.C., hole 25 of Arnould is both offset from and on a different plane as compared to the first hole and second hole, and therefore cannot be "between" the alleged "first hole" and "second hole."

Indeed, in the OsteoMed IPRs, Petitioner persuaded the Board that Arnould's hole 25 "'is not disposed along on the spine, but is part of a separate leg piece that extends off the spine.'" *Stryker Corp.*, IPR2021-01450, Paper 46 at 42 (P.T.A.B. Mar. 8, 2023). If the hole is not "disposed along the spine" of Arnould, then the hole is offset from, not "at, into, or across the space separating," the first and second holes.

---

[8] As set forth in the POR, the Petition simply failed to address this part of [1d]. Having failed to do so, "Petitioner[] may not use reply briefs to cure deficiencies in their petitions." *Intuitive Surgical, Inc. v. Ethicon LLC*, No. 2020-1480, 2022 WL 421189, at *4 (Fed. Cir. Feb. 11, 2022).

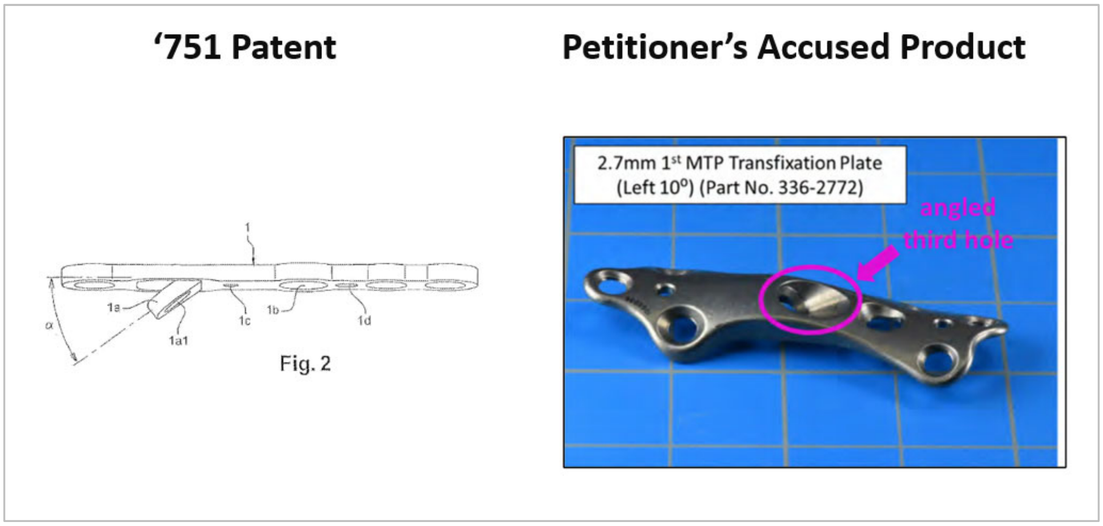
Addressing this issue for the first time on Reply, Petitioner focuses on the figures of the 751 patent, arguing that the angled tab is somehow the same as the leg 20 of Arnould. (Reply, 29). It is not.

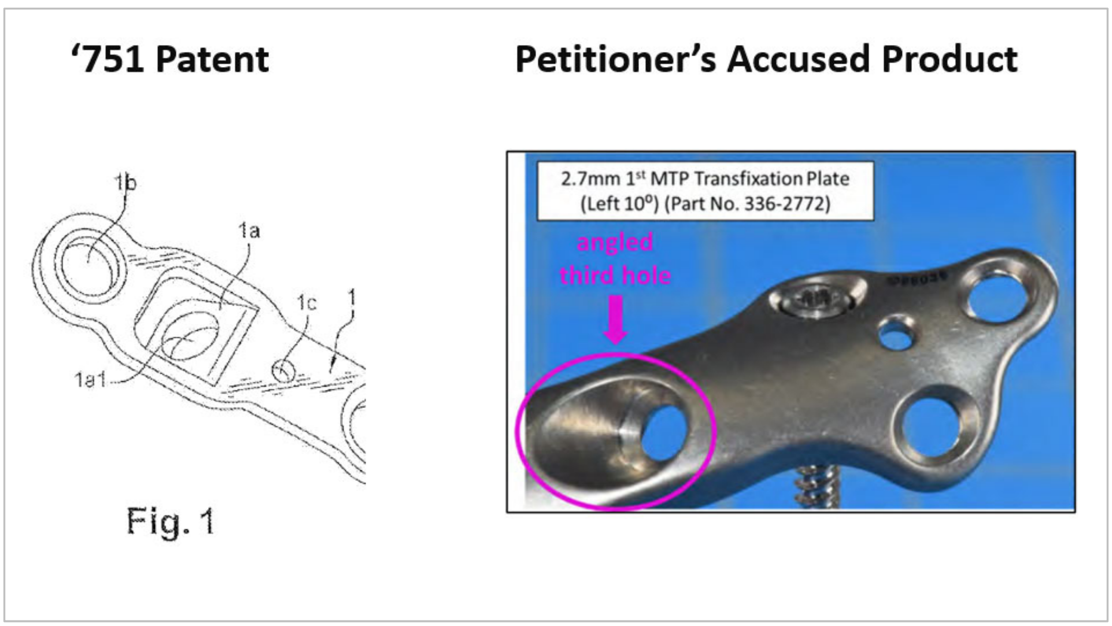


(EX1006, Fig. 1, ¶23, EX1001, Fig. 4). The angled tab is in the space separating the "first hole and the "second hole," whereas hole 25 of Arnould is offset from and plunging downward from the plate body that includes the "first hole" and "second hole."

Mr. Sherman provided no rebuttal to Mr. Leinsing's explanation of why hole 25 of Arnould is not an "angled hole" as claimed. (EX2005, ¶¶270-275). Instead, Petitioner improperly confines the claim to the illustrated embodiment in the 751 patent figures. *Lowe*, 2022 WL 636100, at *6. But the second embodiment

described in the 751 patent, the "angled hole," is not shown in the figures. (EX1001, 1:54-55; 2:20-22). As shown below, an angled tab differs from an "angled hole."





(EX1001, Fig. 1, Fig. 2; EX1020, 20).

As discussed in the POR, a POSITA would not have looked to Zahiri for a "way to provide better compression across the joint," nor does Petitioner provide

any evidence supporting such a conclusion. (POR, 61-67, 75-77). Mr. Leinsing provided unrebutted testimony describing why a POSITA would not have been motivated to combine Arnould and Zahiri, why Arnould teaches away from Zahiri, and why Arnould and Zahiri are not analogous art. (EX2005, ¶¶235-275). The Board should reject Petitioner's new argument, borrowed from [1h], that "[a] POSITA would have looked to Zahiri for a way to improve the integrity of the angled fixation screw," as "fully seating" the screw 30 of Arnould has no apparent relevance to [1d].

B. Claim [11d]/[11h]/[11e]/[11k]

To the extent Petitioner seeks to change invalidity theories from Arnould and Zahiri to Arnould alone, Petitioner's new argument should be rejected. (Reply, 31); *Henny Penny*, 938 F.3d 1324, 1330–31. Petitioner already conceded that Arnould alone does not disclose [11d] and [11h] when it stated that "Arnould is silent regarding the dimensions of hole 25" (Pet., 78, 79-80, 81, 85) and that Arnould does not disclose [11e] and [11k] when it stated that "Arnould is silent regarding the use of temporary fixation members with the guide holes shown in its figures." (Pet., 78-79, 81-82).

Petitioner does not dispute that a POSITA would not be motivated to combine Arnould with Zahiri. (POR, 60-70).

C. Claims 9, 10, 15-18

Petitioner does not separately contest Patent Owner's arguments for claims 9, 10, and 15-18 but instead relies on its arguments for claims 1 and 11.

VII. GROUND 5

As discussed in the POR, Petitioner waived any argument directed to combining Arnould, Zahiri, and Myerson to render obvious dependent claim 6. (POR, 83-96). It is not up to Patent Owner or the Board to have to decipher whether and to what extent Petitioner mistakenly cites its own evidence. *Wasica*, 853 F.3d 1272, 1286–87; *Cloudflare, Inc. v. Sable Networks, Inc.*, IPR2021-0090, Paper 42 at 35 (P.T.A.B. Oct. 18, 2022) ("Although we can use 'common sense and logic to understand the contentions presented in a petition despite typographical errors[,]'[] we cannot add contentions to a petition.").

VIII. CONCLUSION

Petitioner has failed to satisfy its burden in demonstrating that the Challenged Claims are invalid. The Board should find that the Challenged Claims are patentable.

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

OsteoMed LLC
Petitioner,

v.

Stryker European Operations Holdings LLC
Patent Owner

CASE: IPR2022-00488
U.S. PATENT NO. 10,993,751

DECLARATION OF MICHAEL SHERMAN

PCT/FR2009/051879. The National Stage application PCT/FR2009/051879 was filed on October 2, 2009, which in turn claimed prior to foreign application FR0856694A, which was filed on October 2, 2008.

43. I have been asked by counsel to use October 2, 2009 as the priority date of the ’751 Patent. The opinions I offer below regarding the prior art, the combinations set forth in my declaration, or the applicability of those combinations to certain claims of the ’751 Patent do not change whether the ’751 Patent is entitled to an October 2008 priority date, or a priority date of October 2009. I do not offer an opinion, as I have not been asked to offer such an opinion, as to the proper priority date of the ’751 Patent.

A. Summary of the ’751 Patent

44. The ’751 Patent describes and claims a bone plate fixed between two bone parts by way of screws engaged in holes formed in the thickness of the plate. (Ex. 1001, Abstract).

45. The ’751 Patent claims a “system for fusing a first discrete bone and a second discrete bone separated by a joint, … and a third fixation member configured to be inserted through said third hole of said bone plate, into the first discrete bone, across said joint, and into the second discrete bone such that a free end of said third fixation member, not attached to any portion of the bone plate, resides in the second discrete bone.” (Ex. 1001, cl. 1).

65. "[P]ins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1007, 3:10-18).

D. Myerson (Ex. 1010)

66. U.S. Patent Application Publication No. 2006/0241592 A1 to Myerson ("Myerson"), is titled "Mid-Foot Fixation Plate," and published on October 26, 2006. (Ex. 1010, Cover).

67. Myerson discloses a bone plate configured for joint fusion "between the first and second metatarsals and the middle and/or internal cuneiforms." (Ex. 1010, ¶¶5, 10).

68. Figure 1 of Myerson illustrates the bone plate fixed across the tarsometatarsal joint:

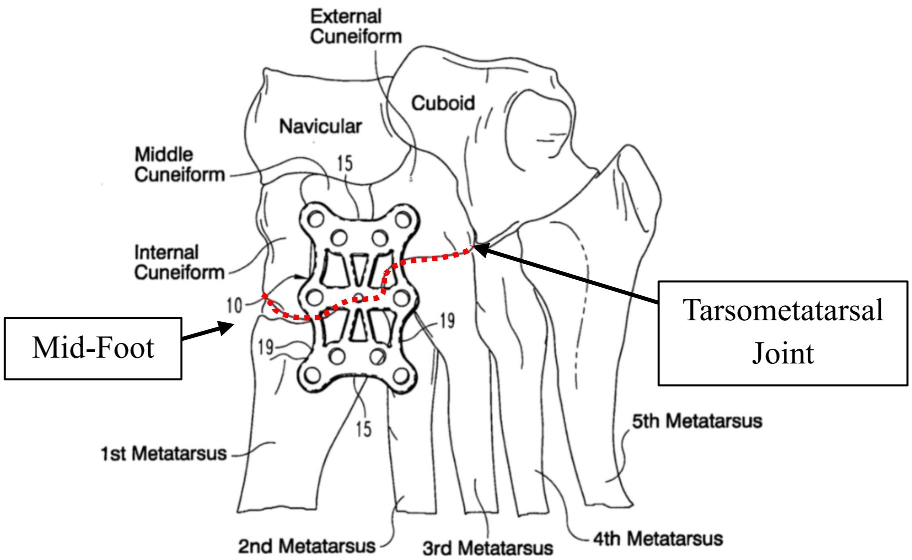


Fig. 1

69. The bone plate is contoured to follow the anatomy of the mid-foot bones and especially across the metatarsal joints. (Ex. 1010, ¶¶21-22).

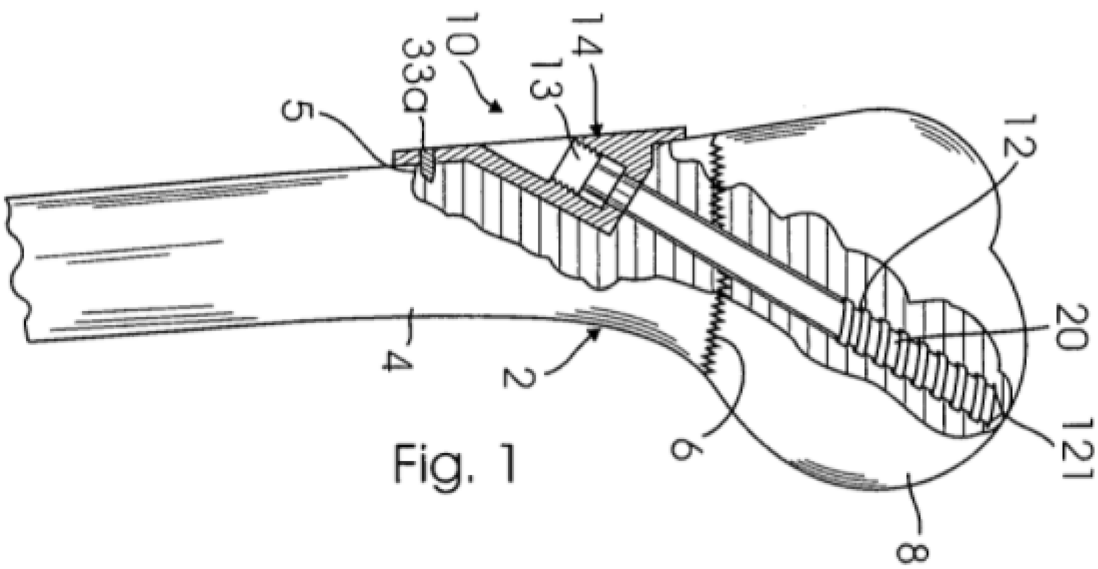
VII. OVERVIEW OF THE CLAIMS

70. I have been asked to give opinions about whether the elements of claims 1-18 of the '751 Patent are disclosed, taught, and/or suggested by Slater, Zahiri, Myerson and Arnould. Below, I have reproduced those claims in their entirety:

[1pre]	A system for fusing a first discrete bone and a second discrete bone separated by a joint, said system comprising:
[1a]	a bone plate having a length sufficient to span the joint, said bone plate having a first end and a second end along said length, said length defining a longitudinal axis, said bone plate defining:

131. Therefore, a POSITA would understand that Slater's bone plate discloses an embodiment of the fixation screw 25 configured to intersect a joint between two discrete bones.

132. However, at the very least, Slater's disclosure guides a POSITA to incorporate the teachings of Zahiri, and position the fixation screw 25 at an angle that contacts only two bone fragments. Zahiri discloses a bone plate configured to fuse a first and second bone part with an angled fixation member oriented to compress the bone fracture:



(Ex. 1007, FIG. 1; *see also* 2:45-48).

133. Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bone parts while dissipating the force so it does not damage the bone parts. (Ex. 1007, 5:65:6-11).

134. A POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to Zahiri when making improvements to Slater's bone plate.

135. Slater contemplates the importance of proper bone plate alignment and guides a POSITA to incorporate the temporary pin holes disclosed by Zahiri into Slater. (Ex. 1004, 4:17-5:9). Slater specifically discloses that "[i]f an arthrodesis or ankle replacement is not properly aligned, significant gait abnormalities may result." (Ex. 1004, 4:23-25).

136. Additionally, Zahiri discloses four small holes in the corner of the bone plate intended for use with pins that temporarily hold the bone plate in place during implantation, as shown in Figure 8:

iii. [1b] said bone plate defining: a first hole at or adjacent the first end, said first hole configured to align with the first discrete bone on a first side of the joint;

142. Slater discloses this element, as explained above in Section VIII.A.2.iii. (*See* Ex. 1004, FIG. 1, 8:15-19, 13:6-9, 13:20-21, 11:28-31, 8:13-14).

iv. [1c] a second hole at or adjacent the second end, said second hole configured to align with the second discrete bone on a second side of the joint; and

143. Slater discloses this element, as explained above in Section VIII.A.2.iv. (*See* Ex. 1004, FIG. 1, 8:22-24, 13:6-12, 8:13-24, 11:5-16).

v. [1d] a third hole located between said first hole and said second hole, wherein said third hole is angled relative to the longitudinal axis of said bone plate;

144. A POSITA would find that Slater discloses this element, as explained above in Section VIII.A.2.v. (*See* Ex. 1004, FIG. 1, 11:19-25, 11:5-16, 11:28-12:2).

vi. [1e] a first fixation member configured to be inserted through the first hole of the bone plate and into the first discrete bone of the joint;

145. Slater discloses this element, as explained above in Section VIII.A.2.vi. (*See* Ex. 1004, FIG. 1, 8:16-19, 11:28-31, 8:13-14).

vii. [1f] a second fixation member configured to inserted through said second hole of said bone plate and into the second discrete bone of said joint;

146. Slater discloses this element, as explained above in Section VIII.A.2.vii. (*See* Ex. 1004, FIG. 1, 8:13-24, 11:5-16).

possibility of modifying the angle α," indicating the surgeon can choose the angle at which the fixation member is inserted to achieve an optimal interface between the screw and the bone. (Ex. 1006, ¶38).

248. While a POSITA may find that Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate, Arnould's disclosure would guide a POSITA to incorporate the teachings of Zahiri, and position the third hole at an angle relative to the longitudinal axis of the bone plate. Zahiri discloses a bone plate configured to fuse a first and second bone part with an angle fixation member and compress the bone fracture:

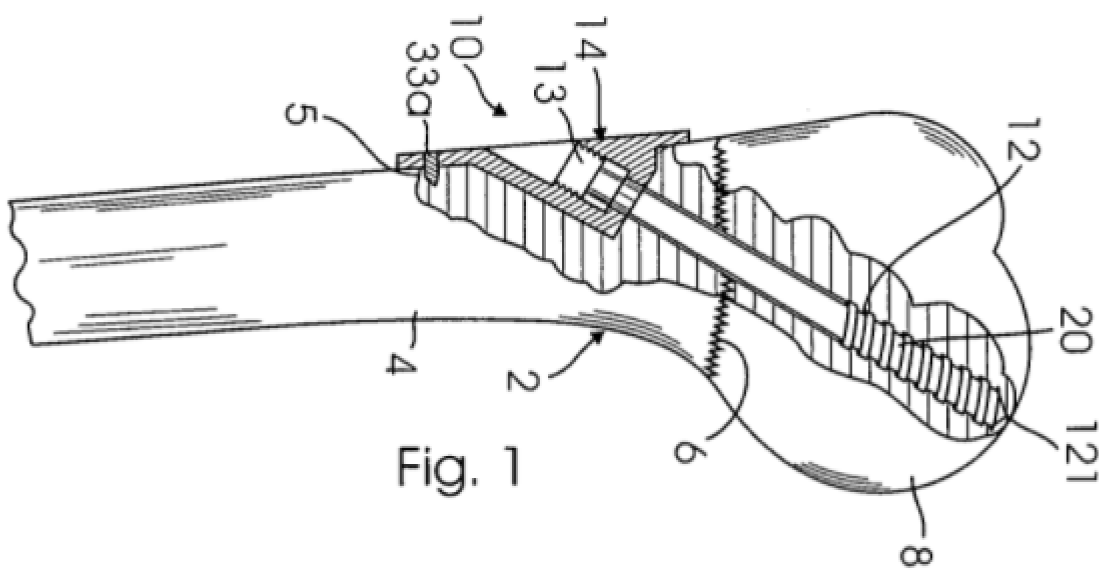


Fig. 1

(Ex. 1007, FIG. 1; 2:45-48).

249. Zahiri further discloses an improved system that allows a sufficient amount of force to be applied between two bone parts while dissipating the force so

it does not damage the bone parts. (Ex. 1007, 5:65:6-11). A POSITA would understand that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate.

250. Additionally, Arnould discloses a method for partially affixing the bone plate to the bone by partially immobilizing the plate using a screw that is not tightened fully in an oblong hole so that the surgeon can correctly position and align the plate. (Ex. 1006, ¶31). Arnould discusses the difficultly of proper plate alignment faced by the surgeon during implantation and the importance that proper placement has on patients' comfort. (Ex. 1006, ¶3).

251. Additionally, a POSITA would understand that Figure 2 of Arnould illustrates temporary guide holes (circled in red below) that are used to temporarily secure the plate during the implantation process:

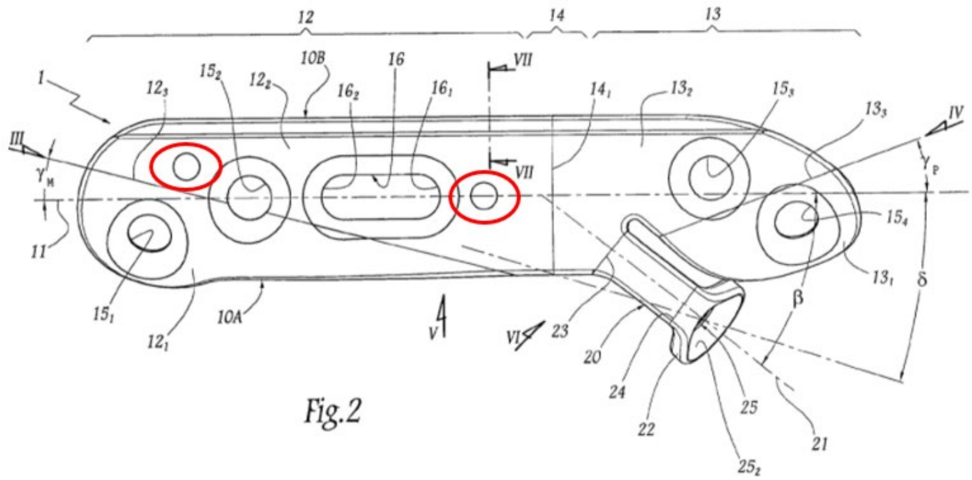


Fig.2

252. (Ex. 1006, FIG. 2 (annotated); *see also* ¶31). While the figures of Arnould show such temporary guide holes, Arnould lack sufficient disclosure regarding the use of temporary fixation members in the guide holes. Thus, a POSITA would look to relevant prior art like Zahiri for disclosure of temporary fixation members known in the art.

253. Zahiri discusses the importance of plate alignment and discloses an improvement that uses temporary locking pins to temporarily secure the bone plate to the bone during implantation. (Ex. 1007, 3:10-18). Zahiri specifically discloses four small holes in the corner of the bone plate that are used with pins to temporarily hold the bone plate in place during implantation:

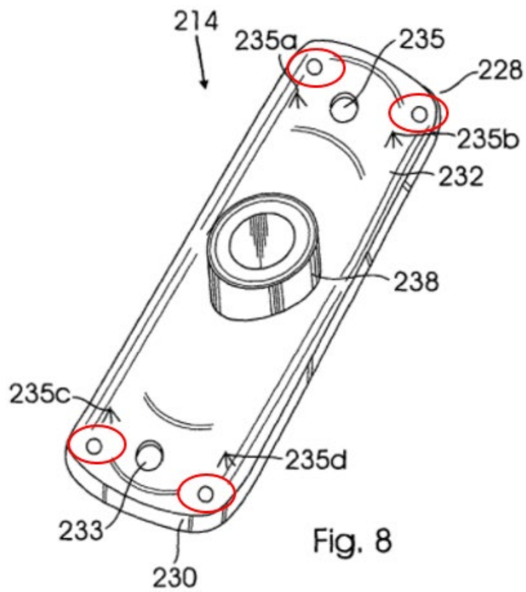


Fig. 8

(Ex. 1007, FIG. 8 (annotated)).

254. Zahiri goes on to state, "pins are designed to temporarily lock in the plate by applying the pins to penetrate through the hole of the plate and partially into the inside of the bone segment so that it creates a user friendly condition for a surgeon to place the disclosed device at a desired location." (Ex. 1006, 3:10-18). The four small holes are used with temporary guide pins that hold the bone plate in place while the lag screw is inserted. (Ex. 1007, 3:10-18). The guide pins ensure proper alignment during implantation and thus prevent discomfort and abnormalities. (Ex. 1007, 3:10-18).

255. As the use of these temporary guide pins would be before the plate is permanently affixed, a POSITA would look to incorporate the improvements disclosed by Zahiri into Arnould to ensure correct placement. (*See* Ex. 1006,

¶¶3, 31). Thus, a POSITA would understand that the temporary guide pins used with pin holes, as disclosed in Zahiri, could be implemented with Arnould's bone plate to temporarily secure the plate alignment during implantation. A POSITA would further recognize that guide holes disclosed by Arnould implicitly teach the use of temporary fixation pins and would render the incorporation of Zahiri's temporary guide pins obvious. (Ex. 1006, FIG. 1). And that Zahiri discloses a known technique for improving plate alignment during implantation.

256. Thus, a POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device) and obtain a similar improvement.

2. Independent Claim 1

i. [1Pre] A system for fusing a first discrete bone and a second discrete bone separated by a joint, said system comprising:

257. Arnould discloses a bone plate configured for arthrodesis of a joint between the first metatarsal and the first phalanx. For example, paragraph 11 of Arnould states, "Figure 1 depicts an arthrodesis plate 1 for a joint between the first metatarsal M and the first phalanx P of the big toe of a left foot." (Ex. 1006, ¶11). Thus, Arnould discloses a system for fusing a first discrete bone and a second discrete bone separated by a joint.

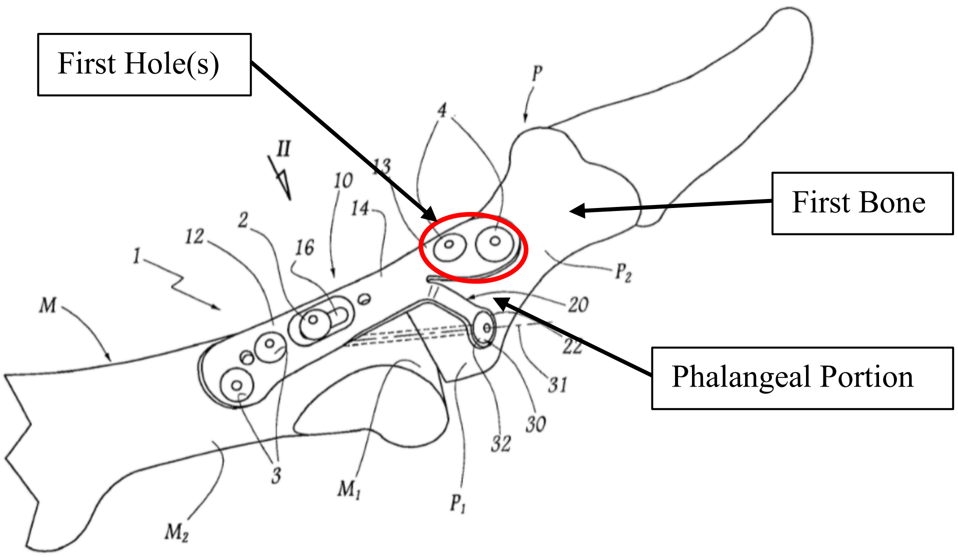


Fig.1

(Ex. 1006, FIG. 1 (annotated); *see also* ¶¶21, ¶34).

260. Based on Figure 1 and the cited specification, Arnould discloses a first hole at or adjacent the first end, said first hole configured to align with the first discrete bone on a first side of the joint.

iv. [1c] a second hole at or adjacent the second end, said second hole configured to align with the second discrete bone on a second side of the joint; and

261. Arnould's bone plate comprises holes 15_1 and 15_2 (second hole(s)) configured to attach to the metatarsal portion 12 (second end) of the plate 1 to the maetatarsal (second bone). The bone plate with the second hole(s), second end, and second discrete bone may be seen in annotated Figure 1 below:

xi. Claim 16: The system of claim 11 wherein the temporary fixation member is a guide pin.

339. For at least the reasons set forth in Section VIII.D.3.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (*See* Ex. 1007, 3:10-18, 7:63-8:11).

xii. Claim 18: The orthopedic implant of claim 17 wherein the temporary fixation is a guide pin.

340. For at least the reasons set forth in Section VIII.D.3.xii, a POSITA would find this claim obvious in view of Arnould and Zahiri. (*See* Ex. 1007, 3:10-18, 7:63-8:11).

E. Ground 5: Claim 6 is Unpatentable Under 35 U.S.C. §103(a) as Obvious over Arnould, Zahiri, and Myerson

341. Dependent claim 6 is obvious in view of the combination of Arnould, Zahiri, and Myerson. Below I explain how each element of claim 6 is disclosed, taught, and/or suggested by the combination of Arnould, Zahiri, and Myerson.

1. Basis for Combination of Arnould, Zahiri, and Myerson

342. A POSITA would be motivated to combine Arnould and Zahiri for at least the reasons set forth in Section VIII.D.1. Additionally, Arnould describes the desire to completely secure the plate to the bone using the screws. (Ex. 1006, ¶¶33-34).

343. In analogous art, Myerson discloses a bone plate for fusion of the MTP joint as well as for receiving a locking screw in combination with threaded holes to lock the fixation screws in place. (Ex. 1010, ¶22).

344. Thus, the use of locking screws or threaded holes to prevent the screws from backing out is a known element to obtain a predictable result in the art. Therefore, incorporating locking screws or threaded holes into Arnould's bone plate can be accomplished through a simple substitution to provide a known advantage and accomplish a predictable result. A POSITA would be motivated to apply the teachings of Myerson and modify Arnould's bone plate.

2. Claim 6: The system of claim 1 wherein said joint is a tarsometatarsal joint.

345. Arnould discloses a bone plate is configured to conform to the anatomical contours of the domed metatarsal zone. (Ex. 1006, ¶15). In analogous art, Myerson discloses a bone plate comprising contours configured to secure the bone plate to various bones "anywhere along the mid-foot," "especially across the metatarsal joints." (Ex. 1010, ¶21-22). Figure 1 of Myerson further illustrates Myerson's bone plate fixed across the tarsometatarsal joint:

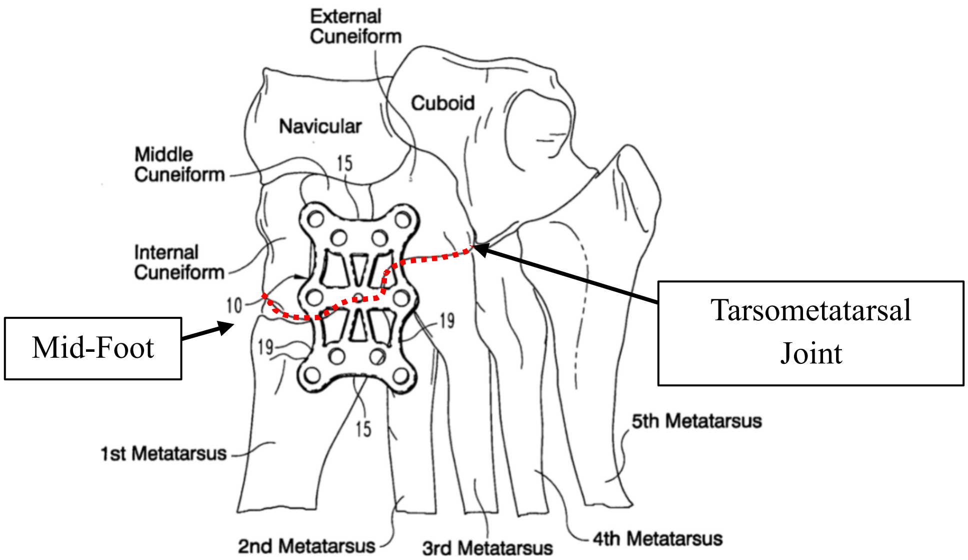


Fig. 1

(Ex. 1010, FIG. 1 (annotated)).

346. Therefore, a POSITA would understand that Myerson's bone plate is configured to fuse the tarsometatarsal joint. Additionally, a POSITA would understand that Arnould's bone plate would easily be configured to contour to the bones in the mid-foot and fuse the tarsometatarsal joint.

347. Based on Figure 1 of Myerson, and the specification cited above, Arnould in view of Zahiri and Myerson clearly discloses a system wherein said joint is a tarsometatarsal joint.

PTO/AIA/15 (10-17)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	TRAUMA 3.12-647 CCCCC
First Named Inventor	Bernard Prandi
Title	Orthopedic Implant In The Form Of A Plate To Be Fixed Between Two Bone Parts
Priority Mail Express® Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

1. [ ] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [ ] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [X] **Specification** [*Total Pages* 6]
   Both the claims and abstract must start on a new page.
   (See MPEP § 608.01(a) for information on the preferred arrangement)
5. [X] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 2]
6. **Inventor's Oath or Declaration** [*Total Pages* 4]
   (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))
   a. [ ] Newly executed (original or copy)
   b. [X] A copy from a prior application (37 CFR 1.63(d))
7. [X] **Application Data Sheet** ** See note below.*
   See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R**
   in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission**
   (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PAPERS

10. [ ] **Assignment Papers**
    (cover sheet & document(s))
    Name of Assignee
11. [ ] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [X] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [X] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [ ] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request**
    Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [X] **Other:** **CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e)**

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

[X] The address associated with Customer Number: 00530 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Wilfred V. Patrick/	Date	January 7, 2021
Name (Print/Type)	Wilfred V. Patrick	Registration No. (Attorney/Agent)	74,814

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4).

Dated: January 7, 2021 Electronic Signature for Wilfred V. Patrick: /Wilfred V. Patrick/

6699501

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	
	First Named Inventor	Bernard Prandi
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	TRAUMA 3.12-647 CCCCC

	31	7799061		2010-09-21	Kay et al.	
	32	8100954		2012-01-24	Kay et al.	
	33	8100983		2012-01-24	Schulte	
	34	2486303		1949-10-25	Longfellow	
	35	4800874		1989-01-31	David et al.	
	36	5487741		1996-01-30	Maruyama et al.	
	37	5853413		1998-12-29	Carter et al.	
	38	5904684		1999-05-18	Rooks	
	39	6379359		2002-04-30	Dahners	
	40	8080010		2011-12-20	Schulz et al.	
	41	7344538		2008-03-18	Myerson et al.	

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	13	20060149261		2006-07-06	Nilsson et al.	
	14	20060241609		2006-10-26	Myerson et al.	
	15	20110004253		2011-01-06	Fraser et al.	
	16	20110306976		2011-12-15	KUBIAK et al.	
	17	20030060827		2003-03-27	Coughln	
	18	20050171544		2005-08-04	Falkner	
	19	20060058796		2006-03-16	Hartdegen et al.	
	20	20060241607		2006-10-26	Myerson et al.	
	21	20060241608		2006-10-26	Myerson et al.	
	22	20070142920	A1	2007-06-21	Niemi	
	23	20070270850	A1	2007-11-22	Geissler	

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	5	1897509	EP	A1	2008-03-12	Surge Foot	English language translation of Abstract only	☒
	6	2007131287	WO	A1	2007-11-22	Slater, Gordon		☐
	7	3027148	DE	A1	1981-12-03	Straumann Inst Ag	English equivalent is US 4,388,921	☒
	8	95016403	WO	A1	1995-06-22	Heggeness Michael H et al.		☐
	9	2846870	FR	A1	2004-05-14	Fixano	English language translation of Abstract only.	☒
	10	2362616	FR	A1	1978-03-24	Duyck, Jean	English translation of Abstract only.	☒
	11	2764183	FR	A1	1998-12-11	Afriat Jacques	English translation of Abstract only.	☒
	12	9528887	WO	A1	1995-11-02	Mortier Jean Pierre		☐
	13	0 705 572	EP	A2	1996-04-10	Synthes Ag, Chur		☐
	14	1707227	EP	A2	2006-10-04	Depuy Products Inc		☐
	15	2912895	FR	A1	2008-08-29	Small Bone Innovations Interna	English translation of Abstract only.	☒

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	41	7344538		2008-03-18	Myerson et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /C.J.B/

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	16	20110306976		2011-12-15	KUBIAK et al.	
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	18	20050171544		2005-08-04	Falkner	
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	20	20060241607		2006-10-26	Myerson et al.	
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	23	20070270850	A1	2007-11-22	Geissler	

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Myerson et al. (43) **Pub. Date: Oct. 26, 2006**

(54) **MID-FOOT FIXATION PLATE**

(76) Inventors: **Mark Myerson**, Baltimore, MD (US); **Priya Prasad**, Warsaw, IN (US); **Roy Sanders**, Tampa, FL (US); **Chris Bremer**, Warsaw, IN (US)

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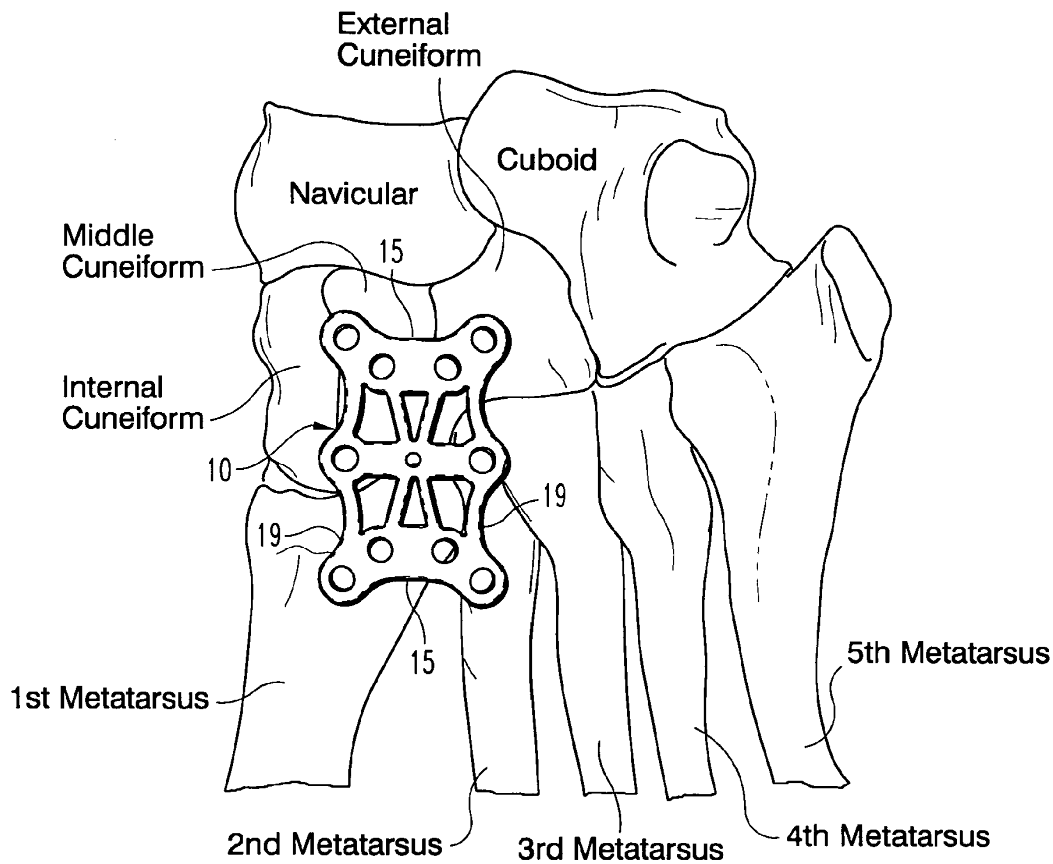
A61F 2/30 (2006.01)
(52) **U.S. Cl.** **606/61**

(57) **ABSTRACT**

A fixation device for fixation and/or fusion of the bones and joints of the mid-foot includes a plate having a plurality of screw holes for attachment of the plate around the perimeter of the fusion site. In one embodiment, four screw holes are positioned at the corners of the plate and two screw holes are located at the opposite sides and mid-length of the plate. Preferably, four additional screw holes are defined at the interior of the plate to increase the number of points of attachment of the plate to the bones of the mid-foot or to increase the ability to stabilize multiple bone segments in the case of a difficult mid-foot fracture. The plate includes a plurality of cut-outs defined between or interior of the screw holes. The cut-outs are sized to accept additional bone fasteners to either enhance the attachment of the plate to the mid-foot bones or to provide access for a fastener to reduce a bone fragment beneath the plate. The plate is configured so that the screw holes and cut-outs are not positioned over a fusion location when the plate is attached to the mid-foot.



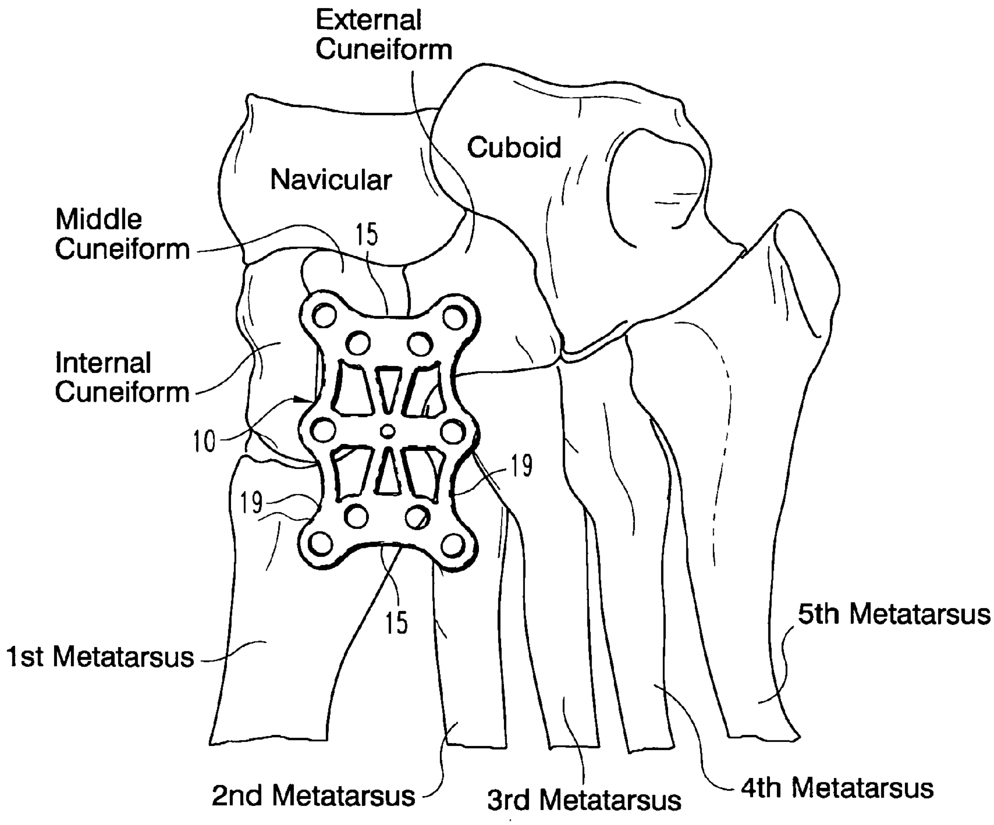

External
Cuneiform
Cuboid
Navicular
Middle
Cuneiform
15
Internal
Cuneiform
10
19
19
15
5th Metatarsus
1st Metatarsus
2nd Metatarsus
3rd Metatarsus
4th Metatarsus

Fig. 1

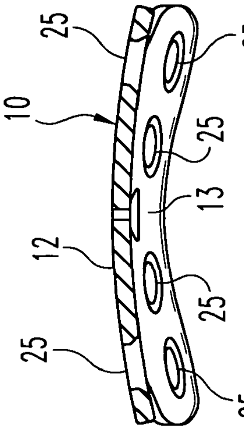


Fig. 4

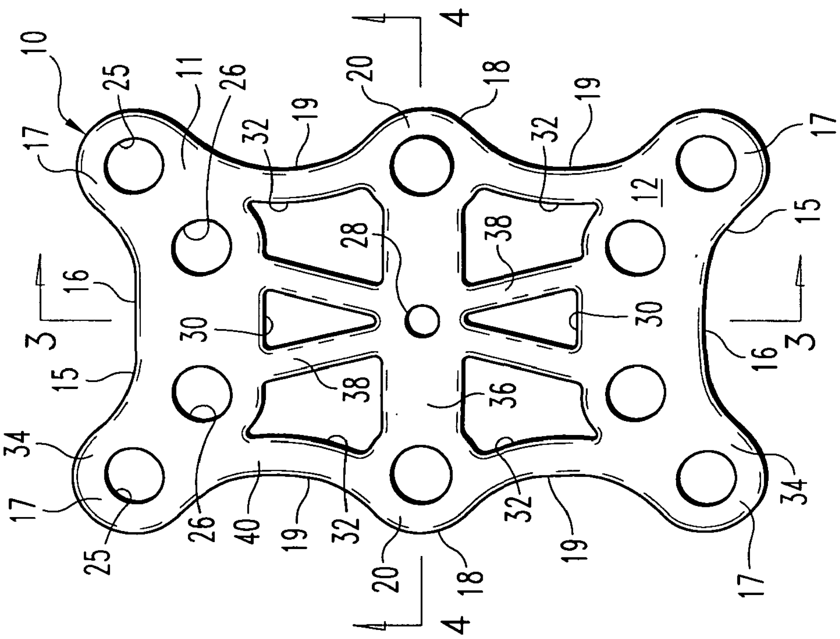


Fig. 2

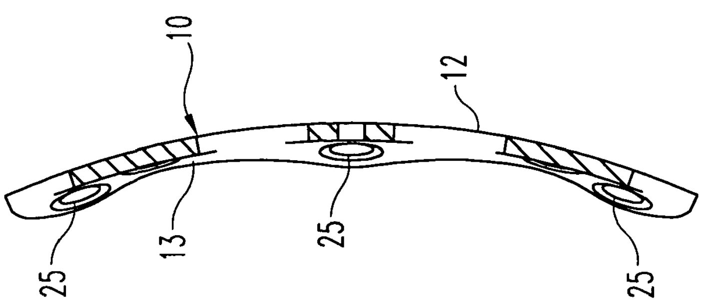


Fig. 3

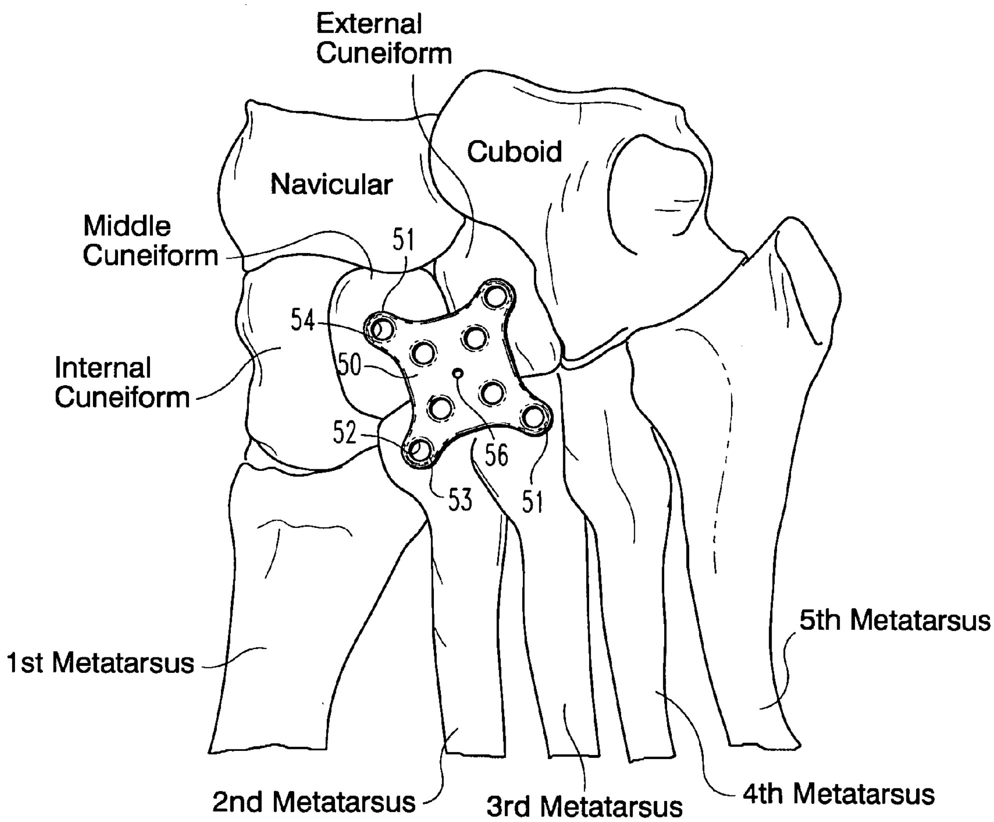

External Cuneiform
Cuboid
Navicular
Middle Cuneiform
51
54
50
Internal Cuneiform
52
56
53
51
1st Metatarsus
5th Metatarsus
2nd Metatarsus
3rd Metatarsus
4th Metatarsus

Fig. 5

MID-FOOT FIXATION PLATE

BACKGROUND OF THE INVENTION

[0001] The present invention relates to plates for fixation of bones and joints. More specifically, the invention pertains to a fixation plate configured for fixation of the mid-foot.

[0002] Trauma to the mid-foot often results in severe fractures and/or dislocations. One such trauma is the well-known Lisfranc injury, which was named after the French doctor who first described the injury during the Napoleonic Wars. The injury identified by Dr. Lisfranc occurred when a horseman fell from the horse with his/her foot caught in the stirrup. The resulting trauma was a fracture of multiple bones of the mid-foot with dislocation of the fragments. In modern times, a Lisfranc injury indicates an injury to the normal alignment of the cuneiforms and metatarsal joints with the loss of their normal spatial relationships. Injuries of this type may occur when a heavy item falls on the mid-foot or from stepping into a small hole and then falling with a twisting imparted to the foot. Athletic injuries are common with sports involving foot bindings, such as windsurfing or snow boarding, or sports where the foot is rotated during impact, such as dancing and soccer.

[0003] The most common Lisfranc injury occurs at the joint involving the 1st and 2nd metatarsals and the medial cuneiform, primarily because there is no connective tissue holding the first and second metatarsals to each other. If the ligaments between the medial and mid-cuneiforms are disrupted, or between the 1st, 2nd metatarsal and the medial cuneiform, then the bones separate and the normal alignment of the joints is lost. Failure to treat a significant Lisfranc injury may result in joint degeneration and even damage to the adjacent nerves and blood vessels.

[0004] Treatment of injuries of this type is usually surgical, especially if a significant separation of the bones exists. One surgical treatment, known as open reduction and internal fixation, usually requires that pins, wires and/or screws be inserted to stabilize the bones and joints and hold them in place until healing is complete. This treatment protocol re-establishes the normal anatomy of the mid-foot while the fractured bones mend. In one typical procedure, a pin or screw is introduced medially into the internal cuneiform and through the base of the second metatarsal bone.

[0005] In some cases, fusion of the joint between the first and second metatarsals and the middle and/or internal cuneiforms may be necessary. Arthrodesis may be indicated where arthritis arises in patients with a prior Lisfranc or similar injury, or where an acute fracture/dislocation has occurred anywhere at the mid-foot.

[0006] The use of pins, staples or screws is often acceptable for younger patients, especially where the injury is not too severe. However, this form of fixation frequently results in non-union in mid-foot arthrodesis attempts, possibly because the bone fragments and/or joints cannot be sufficiently immobilized by pins, screws or staples alone. Consequently, there is a significant need for a fixation device that provides solid fixation and stabilization of a mid-foot injury. Broad treatment possibilities also requires that the fixation device be capable of multiple points of attachment to the mid-foot bones and bone fragments.

SUMMARY OF THE INVENTION

[0007] In view of these needs, the present invention provides a fixation plate that is specifically configured for implantation at the mid-foot. In one embodiment of the invention, a fixation device is in the form of the plate having a plurality of screw holes for attachment of the plate around the perimeter of the fusion site. In one preferred embodiment, four screw holes are positioned in protrusions at the corners of the plate. Two screw holes are positioned in protrusions at the opposite sides and mid-length of the plate.

[0008] In a further preferred feature, four additional screw holes are defined at the interior of the plate to increase the number of points of attachment of the plate to the bones of the mid-foot or to increase the ability to stabilize multiple bone segments in the case of a difficult mid-foot fracture. The four additional screws are oriented within the perimeter defined by the six screws formed in the protrusions.

[0009] In yet another feature of a preferred embodiment of the invention, a plurality of cut-outs are defined in the plate between or interior of the screw holes. In the most preferred embodiment, two generally triangular cut-outs are positioned along the longitudinal axis of the plate inboard of the interior screw holes, and four larger cut-outs surround the triangular cut-outs, but still fall within the perimeter defined by the screw holes. At least the larger cut-outs are sized for passage of additional bone fasteners, such as screws or pins. The cut-outs may be used to provide additional points of attachment or fixation. In addition, the cut-outs may provide access for a fixation pin or screw to reduce a bone fragment underneath the plate.

[0010] The cut-outs are bounded by struts that may be positioned over mid-foot fusion sites or bones to help stabilize the bones or bone segments. The plate is configured so that the screw holes and cut-outs are not oriented over the fusion site(s).

[0011] The protrusions and cut-outs help reduce not only the prominence of the plate, but also the material requirements. The plate is also formed at a minimal thickness that still retains the ability to stabilize the fusion site. In a preferred embodiment, the plate has a thickness of less than 1.0 mm. In order to more accurately conform to the local anatomy, the plate is defined at a spherical curvature, which is preferably at a fixed radius.

[0012] One benefit of the fixation plate of the present invention is that it is much more versatile than prior devices for achieving fusion of the mid-foot. A further benefit is that the plate offers a plurality of options for bone screw placement to stabilize the mid-foot bones and joints, accomplish firm reduction of bone fractures and ultimately ensure union and/or fusion.

[0013] Other benefits and specific objects of the invention will become apparent upon consideration of the following written description taken together with the accompanying figures.

DESCRIPTION OF THE FIGURES

[0014] **FIG. 1** is an enlarged view of the dorsal aspect of the mid-foot with a fixation plate positioned thereon in accordance with one embodiment of the invention.

[0015] **FIG. 2** is a top plan view of the fixation plate shown in **FIG. 1**.

[0016] **FIG. 3** is a side cross-sectional view of the plate shown in **FIG. 2**, taken along line **3-3** as viewed in the direction of the arrows.

[0017] **FIG. 4** is an end cross-sectional view of the plate shown in **FIG. 2**, taken along line **4-4** as viewed in the direction of the arrows.

[0018] **FIG. 5** is an enlarged view of the dorsal aspect of the mid-foot with a fixation plate positioned thereon in accordance with a further embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0019] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

[0020] The bones of the mid-foot are illustrated from the dorsal aspect in **FIG. 1**, along with a fixation plate **10** in accordance with a preferred embodiment of the invention. As can be seen in the figure, the plate **10** spans between the base of the first and second metatarsal bones across to the internal (or medial) and middle cuneiforms. In the embodiment illustrated in **FIG. 1**, a large plate **10** is provided that permits attachment to each of the bones of this portion of the mid-foot.

[0021] Details of the plate **10** may be gleaned from **FIGS. 2-4**. The plate **10** is generally configured from a body **11** of generally uniform thickness and material composition. In the preferred embodiment, the body **11** is formed of a biocompatible material, most preferably a metal. In a specific embodiment, the body material is titanium or a titanium alloy, such as Ti-6Al-4V. In order to reduce the prominence of the plate **10** above the bones of the mid-foot, the plate has a nominal thickness between upper surface **12** and bone engaging surface **13** that is minimized while still retaining sufficient strength to ensure solid fixation of the bones and joints of the mid-foot. In a preferred embodiment, the plate has a thickness of less than 1.0 mm, and most preferably about 0.9 mm. This thickness provides sufficient strength while retaining the ability to bend the plate as required to conform to the geometry of the implantation site. In particular, the plate **10** is configured to be positioned anywhere along the mid-foot, not just at the location shown in **FIG. 1**. Thus, geometry of the middle cuneiform may require a differently contoured plate than a plate positioned across the cuboid bone.

[0022] Preferably, however, the plate does not require any on-site contouring since the bone engaging surface **13** is curved in two dimensions to follow the anatomy of the mid-foot, especially across the metatarsal joints. Thus, as shown in the side cross-sectional view of **FIG. 3**, the surface **13**, and hence the plate **10**, is curved along the length of the plate. The plate is preferably curved at a uniform radius, such as about 75 mm in a specific embodiment. Similarly, the plate is curved across its width, as reflected in the end cross-sectional view of **FIG. 4**. This curvature is also at about 75 mm in a specific embodiment. Most preferably, the entire plate is formed at a spherical radius, which may be about 75 mm in the specific embodiment.

[0023] The body **11** further includes end edges **15** and side edges **19**. In order to reduce material requirements and minimize prominence of the plate **10**, the edges define indentations **16** and **19**, respectively. As shown in **FIG. 1**, the end edges **15** define a single indentation **16** that is flanked on opposite sides of the plate by corner protrusions **17**. These protrusions **17** merge into the indentations **19** at the side edges **18**. A center protrusion **20** is defined on each side edge **18** that is preferably equidistant from each of the corner protrusions **17**. In the preferred embodiment, all of the edges **15**, **18** are rounded to reduce trauma to the soft tissue surrounding the implant plate.

[0024] As shown in **FIG. 2**, each of the protrusions **17**, **20** provides a location for a screw hole **25**. Each screw hole is configured to receive a bone engaging fastener configured to attach the plate **10** to the bones of the mid-foot. In the preferred embodiment, the fastener is a bone screw that is appropriately sized for implantation within the base of the metatarsus, any of the cuneiforms or the cuboid bone. The length and diameter of the screw is generally dictated by the location and the size of the bone or bone fragment being fixed. As shown in FIG. **2**, the plate **10** includes additional screw holes **26** within the interior of the plate. These screw holes **26** increase the versatility of the plate **10** to provide additional attachment points to a given bone, or to provide a path for fixation of a bone segment, such as in the case of a severe fracture.

[0025] The plate **10** of the present invention is specifically configured for implantation and fixation of the mid-foot. Thus, the plate is sized so that the screw holes **25**, **26** are optimally positioned for correction and arthrodesis of numerous mid-foot injuries. In a specific embodiment, the plate has a width dimension of about 21.5 mm between the screw holes in the corner protrusions **17** and intermediate protrusions **20**. The interior screw holes **26** are preferably at a width dimension of about 10.0 mm. The plate **10** has a length between screw holes **25** at the corner protrusions of about 36.8 mm.

[0026] The screw holes **25**, **26** are formed at a diameter commensurate with the size of the bone screw used to attach the plate to bone. In the preferred embodiment, the screw holes are configured for 2.7 mm or 3.5 mm screws that are commonly used for fixation of the bones of the foot. In one feature of the invention, the screw holes may include a circumferential chamfer, such as the chamfer **53** for the screw holes **52** of the plate **50** shown in **FIG. 5**. This configuration of the screw holes allows the plate to accept either size screw at any screw hole location. The present invention further contemplates that the screws may be non-locking or self-locking screws, with the screw holes configured accordingly. In a specific embodiment, locking screws are used and the screw holes **25**, **26** define tapered threads (not shown) of conventional design.

[0027] A further feature of the invention is best seen in **FIG. 2**. In particular, the body **11** of the plate defines a plurality of cut-outs, including two cut-outs **32** on each side

and two central cut-outs **30**, for a total of six cut-outs. The cut-outs **30**, **32** reduce the amount of material used to form the plate **10**. In addition, the cut-outs create opposite end portions **34** and a center portion **36** spanned by struts **38**, **40**. The end and center portions **34**, **36** carry the screw holes **25**, **26**. The struts **38**, **40** help stabilize the bones or bone segments underneath the struts. The portions **34**, **36** and the struts **38**, **40** are configured so that screw holes are not located where fusion must occur to stabilize the mid-foot, as reflected in **FIG. 1**. In the preferred embodiment, the cut-outs **30** are triangular in shape, while the side cut-outs **32** are generally trapezoidal or rectangular in shape. The cut-outs **30**, **32** are dimensioned greater than the diameter of the screw holes **25**, **26**.

[**0028**] In addition to reducing the plate material, the cut-outs **30**, **32** provide additional locations for placement of bone screws to augment the fixation or to connect bone segments. In the former case, the bone screws may be positioned at a corner of any of the cut-outs **30**, **32**. In the latter case, the bone screw is passed through the cut-out and across adjacent bone segments, such as to bridge a fracture. The cut-outs **30** are especially sized to accept a standard bone screw for fixation of mid-foot bone fragments.

[**0029**] In order to facilitate proper placement of the plate **10**, a small diameter hole **28** is defined at the center of the plate **10** in the center portion **36**. The hole **28** is preferably sized to receive a K-wire or other similar guide wire. In an exemplary procedure for correction of a Lisfranc fracture/dislocation, a K-wire may be inserted into the middle cuneiform to guide the plate **10** across the metatarsus-cuneiform spaces. In one aspect of the invention, the plate **10** provides for screw placement around the perimeter of the mid-foot segments to be fused, in particular with screws placed in the screw holes **25** at the protrusions **17**, **20**. In some cases, attachment at these locations is sufficient to adequately stabilize the injury for eventual fusion. In other cases, additional screws may be implanted through the screw holes **26** and even through the cut-outs **30**, **32**. Where bone fragments are present, reduction may be accomplished by passing reduction screws through one or more of the cut-outs **30**, **32**.

[**0030**] For a smaller mid-foot anatomy or a smaller fusion region, the plate **10** may be modified to form a smaller plate **50**, as shown in **FIG. 5**. This smaller plate retains the spherical curvature and minimal plate thickness described above in connection with the larger plate **10**. In addition, the plate **50** includes the corner protrusions **51** which carry the screw holes **52**. Screw holes **54** may be provided at the interior of the plate **50** to increase the versatility of the plate. A K-wire hole **56** may also be provided at the center of the plate. The smaller plate **50** is preferably adapted for patients with smaller mid-foot bone and joint structure.

[**0031**] In the preferred embodiment of the invention, a fixation device is in the form of the plate **10** having a plurality of screw holes for attachment of the plate around the perimeter of the fusion site. In the most preferred embodiment, four screw holes are positioned at the corners of the plate with two screw holes at the opposite sides and mid-length of the plate. Preferably, four additional screw holes are defined at the interior of the plate to increase the number of points of attachment of the plate to the bones of the mid-foot or to increase the ability to stabilize multiple bone segments in the case of a difficult mid-foot fracture. In yet another feature of the preferred embodiment, a plurality of cut-outs are defined in the plate between or interior of the screw holes. In the most preferred embodiment, two generally triangular cut-outs are positioned along the longitudinal axis of the plate inboard of the interior screw holes, and four larger cut-outs surround the triangular cut-outs, but still fall within the perimeter defined by the screw holes.

[**0032**] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A fixation device for fusion of bones or bone segments in the human mid-foot, comprising:

a plate sized for implantation within the mid-foot of a patient, said plate defining a plurality of holes, each having a diameter sized for receiving a bone engaging fastener therethrough for attachment of said plate to bone or bone segments of the mid-foot; and

said plate further defining a plurality of cut-outs, each dimensioned greater than the diameter of said plurality of holes.

2. The fixation device of claim 1, wherein said plate has a substantially uniform thickness less than about 1.0 mm.

3. The fixation device of claim 1, wherein said plurality of screw holes include a circumferential chamfer so the screw holes can receive different sizes of fasteners therethrough.

4. The fixation device of claim 1, wherein said plurality of holes are arranged around the perimeter of said plate.

5. The fixation device of claim 4, wherein said plurality of cut-outs are arranged inboard of each of said plurality of holes.

6. The fixation device of claim 1, wherein said plurality of cut-outs includes a pair of triangular shaped cut-outs arranged along a longitudinal axis of said plate.

7. The fixation device of claim 1, wherein said plurality of cut-outs includes two cut-outs adjacent each side of said plate.

8. The fixation device of claim 7, wherein said two cut-outs adjacent each side are trapezoidal or substantially rectangular in shape.

9. The fixation device of claim 1, wherein said plate further defines a guide wire hole sized to receive a guide wire or K-wire.

10. The fixation device of claim 9, wherein said guide wire hole is disposed substantially in the center of said plate.

11. The fixation device of claim 1, wherein the edges of said plate define a plurality of indentations and protrusions in which at least some of the plurality of holes is defined in a corresponding one of said protrusions.

12. The fixation device of claim 1, wherein said plate includes a bone engaging surface that is curved at a substantially uniform spherical radius.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 10,993,751 B1
APPLICATION NO. : 17/143709
DATED : May 4, 2021
INVENTOR(S) : Bernard Prandi et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Claim 1, Column 3, Line 25, before “inserted through”, insert --be--.

Claim 11, Column 3, Line 65, before “first and second bone parts”, insert --the--.

Claim 11, Column 3, Line 66, delete “;” and insert --:--.

Claim 11, Column 4, Line 3, before “located between the”, insert --hole--.

Claim 11, Column 4, Line 4, delete “fourth hole” and insert --fourth holes--.

Claim 11, Column 4, Line 19, delete “hole” and insert --holes--.

Claim 18, Column 5, Line 2, before “is a guide”, insert --member--.

Signed and Sealed this
Thirteenth Day of July, 2021

Drew Hirshfeld
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC
Patent Owner.

Case No. IPR2022-00488

Patent No. 10,993,751

DECLARATION OF KARL R. LEINSING, MSME, PE IN SUPPORT OF PATENT OWNER'S RESPONSE

28. I understand that a dependent claim incorporates each and every limitation of the independent claim from which it depends. Thus, I understand that if a prior art reference fails to anticipate an independent claim, then that prior art also necessarily fails to anticipate all dependent claims that depend from the independent claim. Similarly, I understand that if a prior art reference or combination of prior art reference fails to render obvious an independent claim, then that prior art reference or combination of prior art references also necessarily fails to render obvious all dependent claims that depend from that independent claim.

C. Claim Construction

29. I understand that "claim construction" is the interpretation of the meaning of patent claims. I understand that claims in this *inter partes* review proceeding are generally given their ordinary and customary meaning, which is the meaning they would have to a POSITA at the time of the invention, in light of the specification and file history.

30. I understand that many sources can be used to assist in understanding the meaning of a claim including the claims themselves, the specification, the prosecution history, and extrinsic evidence concerning scientific principles, the meaning of technical terms, and the state of the art.

31. Intrinsic evidence includes the claim language, language in other claims of the patent, the specification, and the prosecution history. I understand that the

specification informs the proper construction of the claims and may be the most relevant source and best guide to the meaning of a disputed term. I understand that, in some cases, the specification may include a special definition of a claim term by the patent applicant and, in those cases, the patent applicant's special definition would govern. I further understand that, unless required by the claim language or specification, claims should not be limited to the preferred embodiment(s). I understand that extrinsic evidence, which consists of all evidence external to the patent and prosecution history including expert and inventor testimony, dictionaries, and learned treatises, may also be relevant to claim construction. I also understand, however, that it cannot be used to vary the terms of the claims or otherwise contradict the intrinsic record, and that extrinsic evidence is less significant than the intrinsic record in determining the meaning of claim language.

32. I have been asked to review the claims and ascertain the meaning of the claims from the perspective of one of ordinary skill in the art. My opinions on claim construction expressed in this declaration are from the perspective of a POSITA as of October 2, 2008, the priority date of the 751 patent, and are consistent with my understanding as stated above with regards to this *inter partes* review.

33. Mr. Sherman states that he has "treated each claim term as it would be understood to have its plain and ordinary meaning to a POSITA." (EX1002, ¶25). However, by failing to define certain claim terms, Mr. Sherman's obviousness

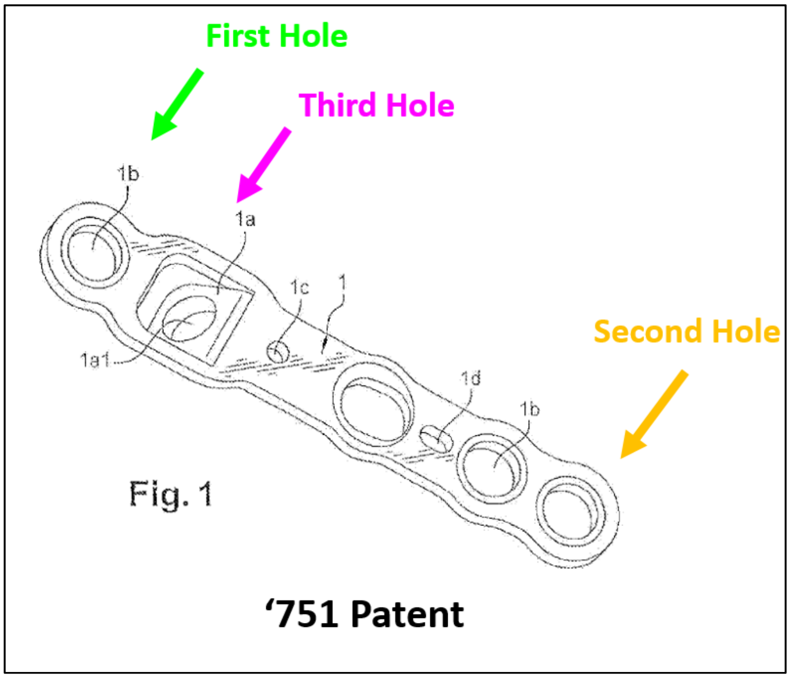
analysis overlooks certain claim limitations that are not met by the prior art.

34. For example, each of the challenged independent claims 1, 11, and 17 recites a "bone plate." (EX1001, cls. 1, 11, 17). The 751 patent defines the claim term "bone plate" as "a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts." (*Id.*, 1:29-31). This is consistent with the dictionary definition of "bone plate," which contemplates "a metal bar with perforations for the insertion of screws, used to immobilize fractured segments" (EX2012) or "a metal plate used to reconstruct a bone that has been fractured. The plate is designed to hold bone fragments in apposition." (EX2013). This is also consistent with Mr. Sherman's Declaration, which walks through the history of bone plates and depicts bone plates designed to be fixed between two bone parts. (EX1002, ¶¶34-40). Dr. Holmes has further opined that "a 'bone plate' generally refers to a plate that is positioned to span a joint or fracture where the plate includes holes through which bone screws can be engaged into the bone parts on each side of the joint or fracture. Bone plates are generally made of metal but can also be made of non-metal materials such as polyethetherketone (PEEK) and provide structural support to the bone(s) on either side of the joint or fracture." (EX2007, ¶¶19-20). Thus, a POSITA would have understood the claimed "bone plate" to refer to "a plate designed to be fixed between two bone parts to immobilize a fracture or joint."

35. Independent claim 1 recites a bone plate having a "first end" and a

"second end." (EX1001, cl. 1). While the specification does not define the terms "first end" and "second end," a POSITA would have understood such terms to demarcate the boundaries of the claimed bone plate. The dictionary definition of "end" is "the furthest or most extreme part of something." (EX2014). As such, a POSITA would have understood that the claimed "first end" to refer to one end of the bone plate and the "second end" to include the opposite extreme end of the bone plate.

36. Finally, each of the challenged independent claims recites a bone plate having a "third hole" located "between" a first hole and a second hole. (EX1001, cls. 1, 11, 17). The claim term "between" should be construed in a manner consistent with its ordinary meaning to a POSITA at the time of the invention. Here, the ordinary meaning of "between" is "at, into, or across the space separating two objects, places, or points." (EX2015). A POSITA would understand that "a third hole located ***between*** said first hole and said second hole," refers to a "third hole" located in the space separating the first hole and the second hole. This is consistent with the 751 patent, which illustrates a "third hole" located in the space separating the "first hole" and the "second hole." (EX1001, Fig. 1).



(EX1001, Fig. 1, cls. 1, 11, 17).

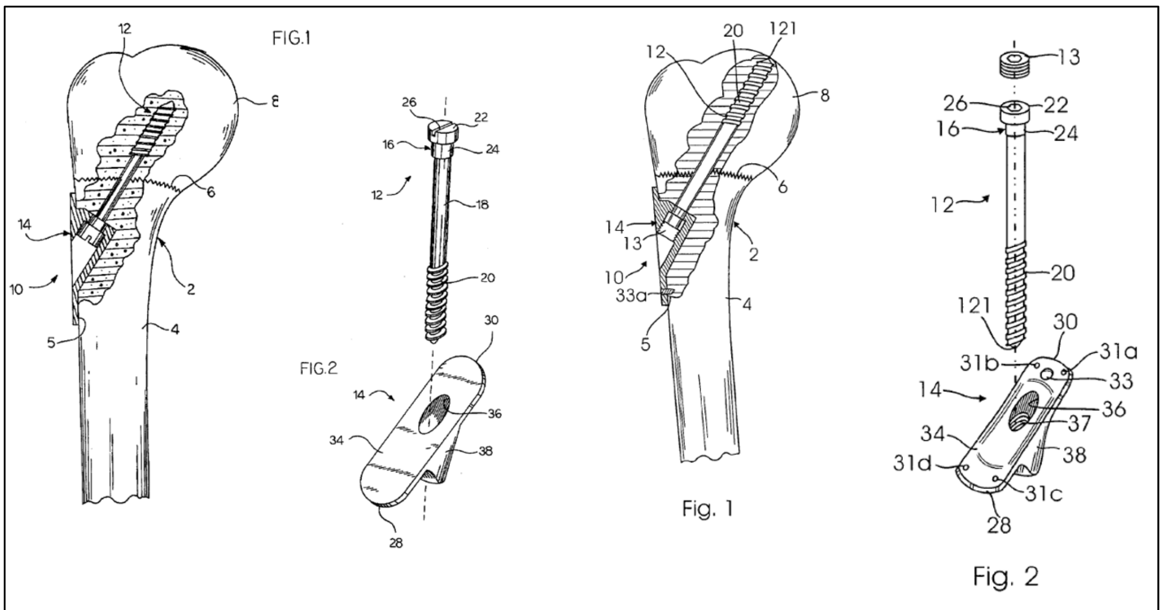
VI. LEVEL OF ORDINARY SKILL IN THE ART

37. I have been asked to analyze the 751 patent and the references discussed herein from the perspective of a POSITA at the time of invention. I understand that, for purposes of this *inter partes* review, the time of invention is assumed to be the 751 patent's priority date, which is October 2, 2008.

38. I understand that POSITA of the 751 patent is a hypothetical person who is presumed to be aware of pertinent art including knowledge in the art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. I understand that this hypothetical POSITA is considered to have the normal skills and knowledge of a person in the technical field.

C. Zahiri U.S. Patent No. 8,187,276 B1 (EX1007)

76. Zahiri U.S. Patent No. 8,187,276 B1 is entitled "Odd Angle Internal Bone Fixation Device for use in a Transverse Fracture of a Humerus," and is directed to an improved fixation device for both a transverse and longitudinal fracture located at the junction of the metaphysis and diaphysis of a long bone such as the proximal humerus. (EX1007, 2:16-20). Zahiri describes several improvements that it made to its prior art device disclosed in U.S. Patent No 5,693,055 ("the 055 patent"). (EX2010).



Predecessor Zahiri Device **"Improved" Zahiri Device**

77. Both the predecessor disclosed in the 055 patent and the so-called "improved" Zahiri devices include an elongated lag screw and a rectangular guide plate with a short barrel integrally attached thereto. (EX1007, Fig. 1; 6:12-13, 6:30-

32; EX2010, 3:61-4:5). The guide plate "serves as a guide for the lag screw and allows the engagement of the head of the lag screw with the inner wall of its short barrel portion." (EX1007, 2:31-33; EX2010, 3:66-4:1). The guide plate directs a lag screw at a fixed angle "through the diaphyseal segment of the fracture…cross fixing the respective bone longitudinal and transverse fracture line and settling in the depth of the epiphysis." (EX1007, 2:22-28, 2:56-58; EX2010, 7:19-12). The Zahiri guide plate, which is positioned on one side of a fracture, is "designed to be able to aid in making a guide hole at a desired angle so that the lag screw can be turned into the bone at the desired angle following the guide hole." (EX1007, 2:51-54).

78. The predecessor device of the 055 patent was deemed to be an improvement over then-existing art because the fixation of the guide plate was provided by the main lag screw, thus eliminating the need for additional fixation screws to maintain the guide plate against the bone cortex. (EX2010, 4:57-62). With the guide plate only needing to accommodate one fixation screw, use of the device required only a small skin incision and minimal tissue dissection. (*Id.*, 7:35-39).

79. According to Zahiri, the predecessor device of the 055 patent suffered from problems with loosening of the lag screw, difficulty in precisely following a desired angle for the lag screw, and stabilizing the plate when the lag screw is pushed and turned into the bone. (EX1007, 1:51-2:8). The purported improvements of Zahiri include, for example, "a newly designed hollow cylinder placed inside of the

barrel of the guide plate, [such that] the guide plate can be further used to help make a guide hole on the bone for guiding the lag screw precisely to settle into the bone at a desired angle." (*Id.*, 3:26-31).

Zahiri

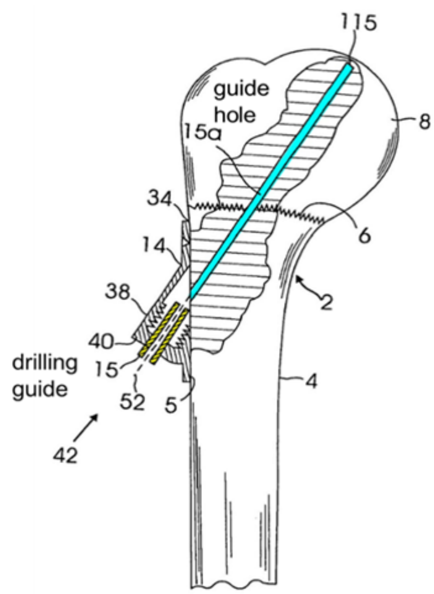


Fig. 6

80. Moreover, the Zahiri lag screw features a cylindrical head having a hexagonal cavity to accommodate a driving tool to drive the lag screw into the epiphysis. (*Id.*, 2:23-31, 5:8-11). Zahiri further provides for a locking screw that is placed "on top of the lag screw settled inside of the bone to stabilize the position of the lag screw immediately after surgery." (*Id.*, 3:47-50, Fig. 1, Fig. 2 (locking screw 13)).

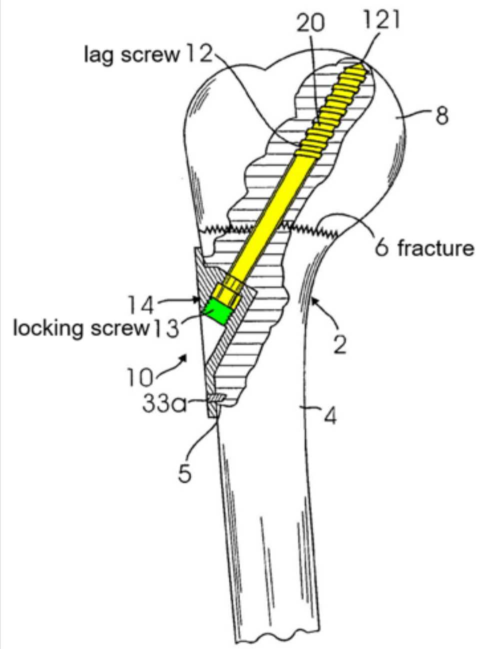


Fig. 1

81. Finally, "the improved odd angle internal fixation device further contains newly designed four pins and one or two additional screws through the plate as well as four tips on the front side of the guide plate. The pins are used to aid in locating the plate at a position of the diaphysis cortex of the humerus, and are also used to stabilize the plate during a surgical operation when the lag screw is pressed and turned into the humerus. The pins are removed after the lag screw is settled inside the epiphysis." (*Id.*, 2:37-45). "The four tips are also able to lock the plate when they are pressed into the bone cortex after the lag screw is engaged into the

depth of the epiphysis." (*Id.*, 2:48-50).

Zahiri

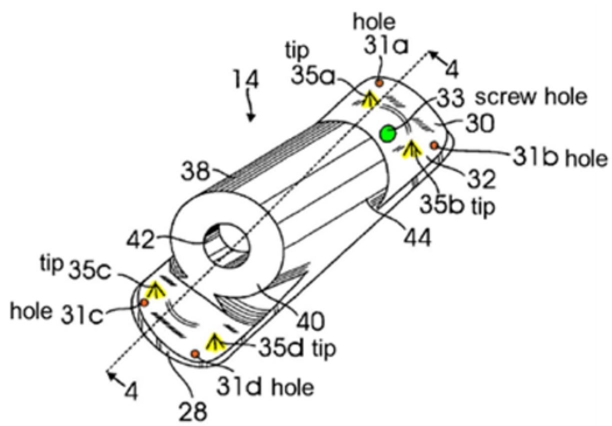


Fig. 3

82. Furthermore, Zahiri explains that the barrel portion, which is "integrally attached to the guide plate 14," is defined by opening 42 on the distal end 40 and proximal end opening 46 on the proximal end 44. (*Id.*, 6:12-18). The barrel portion of Zahiri is further defined by a series of walls that make up the "cylindrical hollow structure," including, opening side wall 42, inner cylindrical wall 41, threaded side wall portion 37, and inner side wall 48." (*Id.*, 6:14-18). Inner cylindrical wall 41 and threaded side wall portion 37 include specific lengths "defined between the first point 1 and the second point 2," and "the second point 2 to a third point 3," respectively. (*Id.*, 6:18-24).

Zahiri

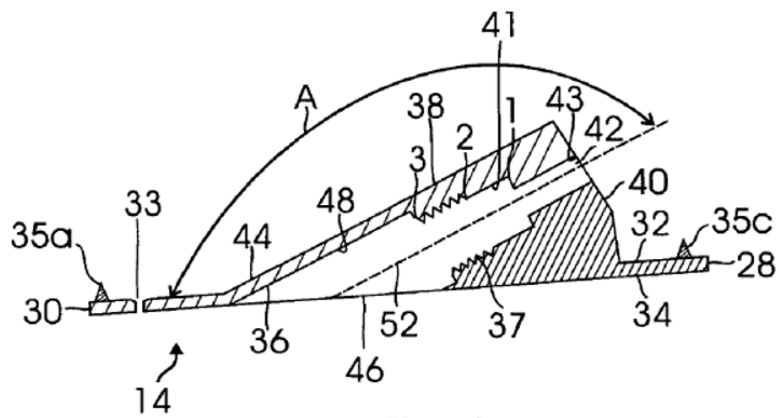


Fig. 4

(*Id.*, Fig. 4). For inner cylinder wall 41, the length between the first point 1 and the second point 2 is equal to "the height of the proximal head 22 of the lag screw 12." (*Id.*) For threaded side wall portion 37, the length between the second point 2 to a third point 3 is slightly less than "the height of the locking screw 13." (*Id.*).

D. Myerson U.S. Patent Appl. Pub. No. US 2006/0241592 A1 (EX1010)

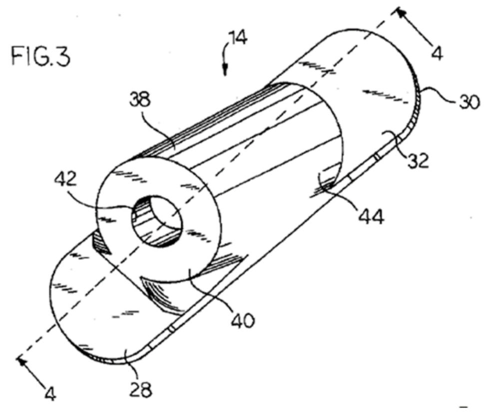
83. Myerson U.S. Patent Appl. Pub. No. US 2006/0241592 A1 ("Myerson") is directed to a fixation device for fusion of bones in the mid-foot. (EX1010, Abstract, ¶1). In particular, Myerson discloses a plate that "is specifically configured for implantation at the mid-foot." (*Id.*, ¶7; *see also id.*, ¶25 ("The plate 10 of the present invention is specifically configured for implantation and fixation of the mid-foot.")). Myerson purports to provide "a plurality of options for bone screw placement to stabilize the mid-foot bones and joints." (*Id.*, ¶12). "Thus, the

3. Mr. Sherman's Combination is Based on Hindsight

146. Mr. Sherman also purports to incorporate Zahiri's temporary pin holes into Slater's plate and concludes that "a POSITA would be motived to combine the teachings of Slater and Zahiri, to utilize a known technique for improving the implantation of a bone plate (similar device), and obtain a similar and predictable improvement." (EX1002, ¶¶135-139). I disagree.

147. The "temporary pin holes" and "four tips" were added to the Zahiri device because its predecessor device (described in U.S. Patent No. 5,693,055 ("The 055 patent") was "unstable in operation when the lag screw [was] pushed and turned to settle into the bone." (EX1007, 1:51-57, 5:52-59). The odd angle internal device disclosed in the '055 patent would torque, or spin on the surface of the humeral cortex as the lag screw was advanced into the bone. When it came to improving Zahiri, "[a]n appropriate structural fixture designed for the plate [was] necessary to make it easily lock at a position on the diaphsis [sic] cortex and further keep it stable during operation when the lag screw [was] pushed and turned into the bone structure." (*Id.*, 1:57-61). As a result, holes such as 31a, 31b, 31c, and 31d, along with the "four tips" were included in Zahiri to "stabilize the guide plate against the bone cortex at a position for a surgical process." (*Id.*, 3:41-44).

The '055 Patent



Zahiri

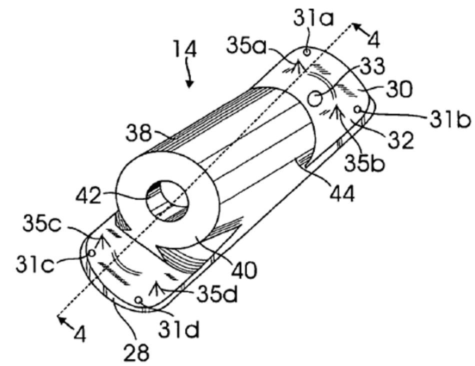


Fig. 3

(EX2010, Fig. 3; EX1007, Fig. 3).

148. Unlike the guide plates disclosed in the '055 patent and Zahiri, Slater's plate is not at risk for unwanted torqueing or spinning because (1) unlike the bulbous head of a proximal humerus, the ankle joint is relatively flat (EX2007, ¶¶31-33, 46-53, 57-62); (2) the Slater plate is anatomically contoured to the tibia and the talus (EX1004, Fig. 1, Fig. 2); and (3) Slater's plate already includes additional holes such as holes 99 and 100 into which a screw may be partially inserted to position the plate prior to insertion of the lag screw. (EX1004, Fig. 1, Fig. 2, Fig. 6, 14:8-9; EX2006, ¶¶31-33, 46-53, 57-62).

149. For example, Slater expressly states that "openings 99 and 100 are elongated to allow alignment adjustments." (EX1004, 14:8-9). A POSITA would understand that openings 99 and 100 may be used to position the bone plate prior to inserting lag screw 25 through opening 93. (EX2007, ¶¶31-33, 46-53, 57-62).

and second bone. . . . Arnould and Zahiri are therefore in analogous fields of invention." (*Id.*, ¶245). I disagree.

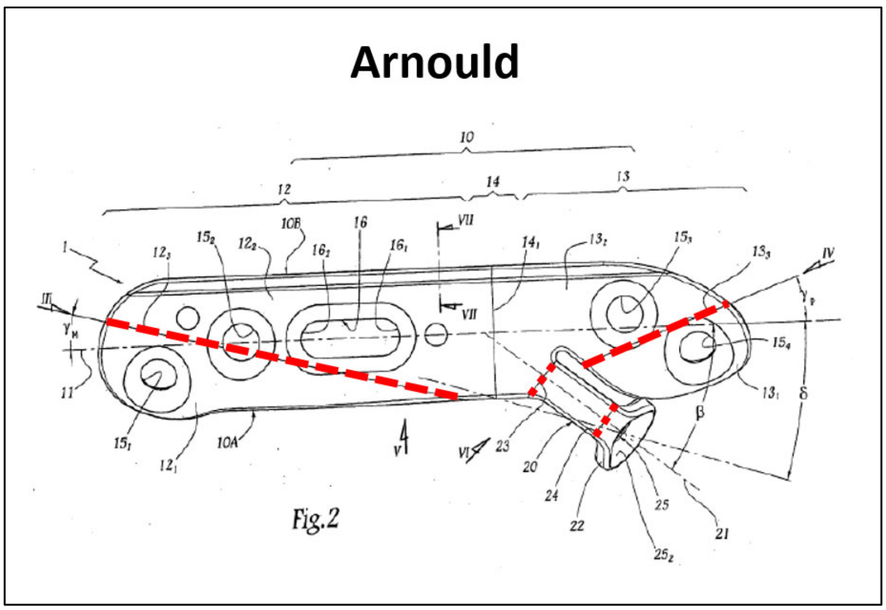
238. Arnould is directed to a bone plate for fusing a metatarsophalangeal joint where the surgeon is provided with flexibility to select an appropriate screw angle to ensure proper fusion. (EX1006, ¶1). While Arnould discloses a bone plate, Zahiri discloses a guide that directs a lag screw at a precise angle into a humeral head, not a bone plate. ([claim construction]). The Zahiri device is directed to a completely different function than Arnould. For the reasons explained above in Ground 2, Zahiri is not directed to a "bone plate" as claimed and is therefore, non-analogous art. (Section XI.A.1). Moreover, Zahiri is not "configured to compress the intersection of a first and second bone," as Zahiri is not directed to arthrodesis but rather to guiding a lag screw to compress bone fragments of a proximal humerus fracture. (EX1007, 2:51-54, 3:26-31, 6:49-67, 7:4-9, EX2009, 134:14-19). Thus, a POSITA would not have been motivated to combine Arnould and Zahiri because Arnould and Zahiri are not analogous art.

2. Arnould Teaches Away From Zahiri

239. Mr. Sherman opines that "Arnould's disclosure would guide a POSITA to incorporate the teachings of Zahiri." (EX1002, ¶248). In my opinion, Arnould's disclosure does not guide a POSITA to Zahiri because Arnould teaches away from Zahiri. In fact, combining Zahiri with Arnould would remove a surgeon's ability to

adjust the Arnould plate to a patient's anatomy.

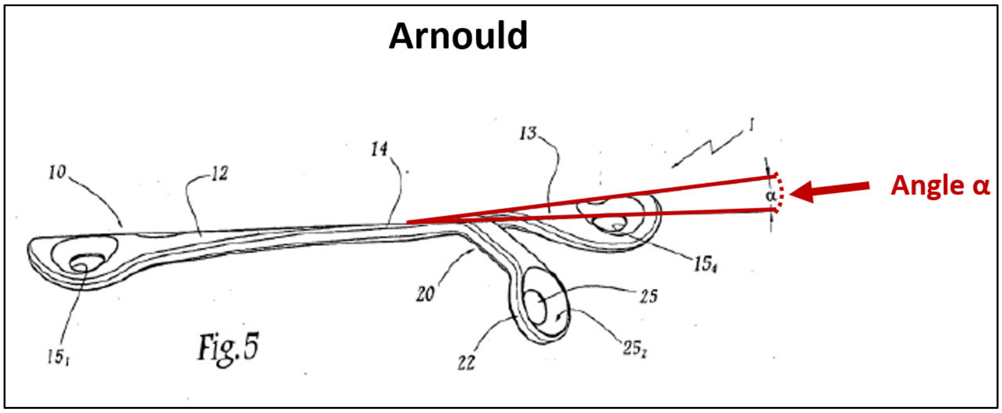
240. The Arnould plate is specifically designed to straddle the metatarsophalangeal joint, "particularly for the joint between the first metatarsal and the first phalanx of the big toe" such that fixation screws can be placed in both the metatarsal and the phalanx. (EX1006, ¶1). Due to the shape and contours of the first metatarsal and the proximal phalanx, as well as the angle between the two bones, the thin Arnould plate is designed to be bent and folded to conform to the anatomy. (*Id.*, ¶¶15, 16, 17, 20, 23, 24, 25, 38, 39). I have indicated the referenced fold lines of Arnould below:



(*Id.*, Fig. 2).

241. Arnould also discloses that the surgeon can adjust the angle between the metatarsal portion 12 and the phalangeal portion 13 of the plate body 10 to match

"the anatomical angle of dorsiflexion between the metatarsal M and the phalanx P of the patient being operated on, taking into account, in particular, the bone resections and the general morphology of the patient's bones, as well as his or her footwear habits and, more particularly, the height of the shoe heel." (*Id.*, ¶¶20, 38).



(*Id.*, Fig. 5).

242. However, when asked whether a surgeon could use plate benders to modify Zahiri, Mr. Sherman confirmed that Zahiri does not share the same pliable aspects as the Arnould plate. (EX2009, 158:7-13 ("Q. Could a surgeon use plate benders to modify Zahiri? . . . A. I don't know that Zahiri addresses it, but probably not. It just generally appears to be too short of a space and intended to be on a flat surface as well.")). I agree with Mr. Sherman. A POSITA would understand that Zahiri could not be adjusted to a patient's anatomy in the same way as Arnould.

243. In making the alleged combination, Mr. Sherman states only that "Zahiri discloses an improved system that allows a sufficient amount of force to be

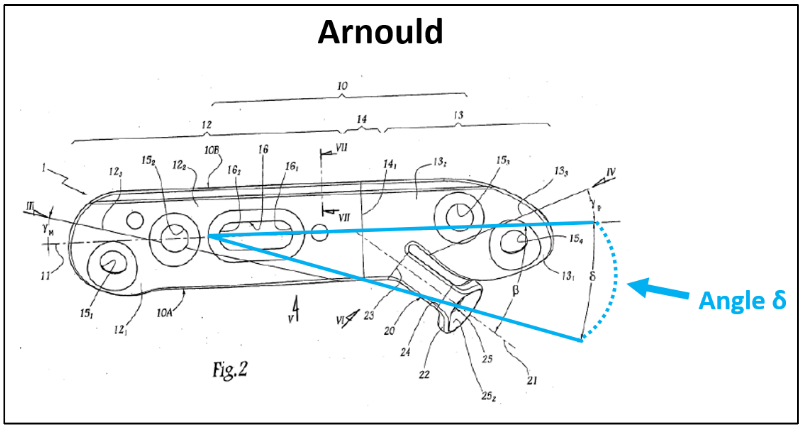
applied between two bone parts" but nowhere does he opine on how combining Zahiri with Arnould would effect a surgeon's ability to contour and adapt the Arnould plate according to a metatarsophalangeal joint. (EX1002, ¶249). Of course, according to Mr. Sherman, Zahiri is not actually an "improved system" so it remains unclear why a POSITA would have been motivated to combine Zahiri with Arnould in the first place. (EX2009, 134:17-19 ("[i]f I said Zahiri is an improved system, I misspoke because Zahiri is . . . not focused at arthrodesis.")).

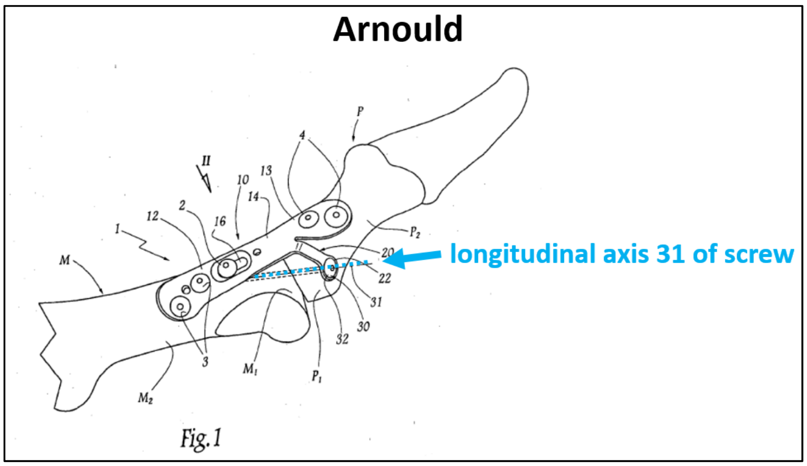
244. Mr. Sherman concedes that "Arnould does not expressly disclose the angle of the third hole positioned relative to the longitudinal axis of the bone plate" and therefore combines Zahiri's "third hole at an angle relative to the longitudinal axis of the bone plate." (EX1002, ¶248). Mr. Sherman also states that "Zahiri discloses a bone plate configured to fuse a first and second bone part with an angled fixation member and compress the bone fracture." (*Id.*). However, a POSITA would understand that incorporating Zahiri's barrel portion into Arnould takes away the ability to select multiple trajectories for screw 30 of Arnould.

245. As discussed above in Section XI.A.2., Zahiri teaches that the barrel portion and guide plate are set at a fixed angle, which permits only one angle for the lag screw. (EX1007, Fig. 4, Fig. 5, Fig. 9, 2:23-28, 2:31-33, 3:26-31, 3:53-58, 6:12-25, 7:24-29, 7:31-35). For example, Zahiri discloses that "[t]he lag screw 12 is then slidably received within the passage 52 of the barrel portion 38 from the back 25

side 34 of the guide plate 14, where the interior of the short barrel portion 38 is designed so that the lag screw 12 engages into the barrel portion 38 at three different diameters of the passage 52." (*Id.*, 7:24-29). The engagement between the geometry of Zahiri's lag screw and the barrel portion limits a surgeon's ability to insert the lag screw within a range of angles. (*Id.*, *see also id.*, 6:12-35). This in direct contradistinction to hole 25 of Arnould which permits a range of multiple trajectories for screw 30. (EX1006, ¶¶27, 28). Even Mr. Sherman admitted that Arnould's screw can be inserted within a range of trajectories. (EX2009, 67:24-68:8 ("I think the screw can go in and move through a range [of] trajectories." Q. Setting aside whether we're talking about delta or beta, you would agree with me that the screw can go in at different trajectories of the screw, for instance? A. I think that's correct.")). While Arnould discloses that a single bone plate is capable of achieving a range of multiple trajectories for the screw, Zahiri discloses three embodiments, each including a barrel portion fixated at one of three separate angles: 90 degrees, 150 degrees, or 160 degrees. (EX1007, 2:23-28, Fig 4, 4:24-25, Fig. 5, 4:28, Fig. 9, 4:43; *see also* Section XI.A.2.)).

246. In particular, Arnould discloses that the screw is "inserted into the hole 25, following a direction of insertion inclined in relation to the plate body 10 at angle δ." (EX1006, ¶32). As shown below, δ is formed by the longitudinal axis 31 of the screw and the longitudinal direction 11 of the plate body 10. (*Id.*, ¶27).



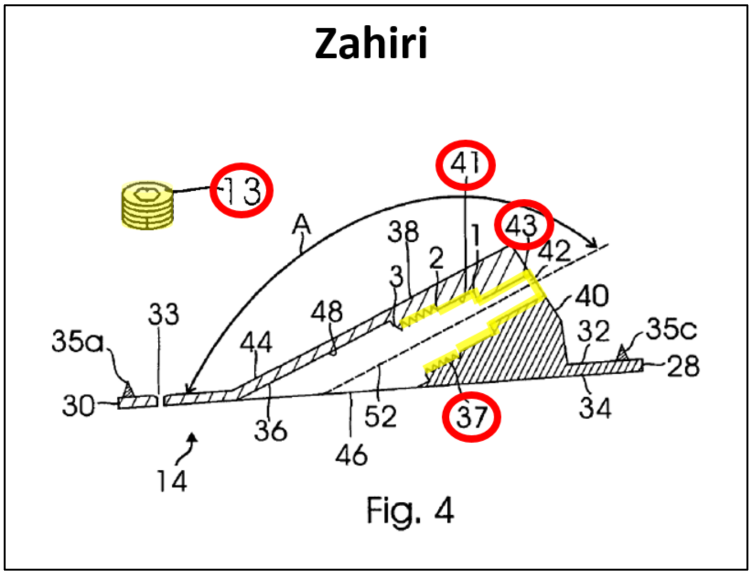


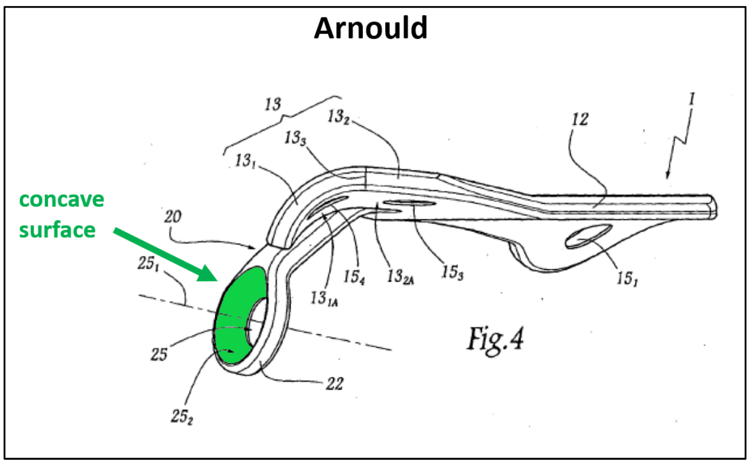
(*Id.*, Fig. 1, Fig. 2).

247. Arnould also discloses that angle δ "is chosen by the surgeon so that that this screw, during its screwing, successively passes through the phalangeal epiphysis P1 and the metatarsal epiphysis M1." (*Id.*, ¶32). Mr. Sherman acknowledges this and states that "Arnould further discloses a variable fixation angle . . . selected by the surgeon." (EX1002, ¶247). Zahiri, however, does not provide the surgeon with the same flexibility. (EX2009, 90:24-91:9). If combined with Arnould, a POSITA would understand that a surgeon would not be able to choose

from among the multiple screw trajectories afforded by hole 25, defeating one of the main advantages of the Arnould plate.

248. Moreover, Zahiri teaches structural features that confine the head of Zahiri's lag screw within the barrel. Features such as Zahiri's inner cylindrical wall 41, opening side wall 43, threaded side wall 37, and locking screw 13, which "is introduced on top of the lag screw head to securely lock the lag screw," are incompatible with the Arnould plate. (EX1007, 6:14-30, 2:28-31; EX2009, 95:24-96:8). For example, including Zahiri's locking screw on top of the lag screw would require that leg 20 of Arnould be even larger and more prominently protruding from the surface of the bone plate. As compared to Zahiri, hole 25 of Arnould includes edge 25_2, which is described as "a concave surface" that permits the head of the screw "to rest and wedge against at least a portion of the edge 25_2, even if [the screw] axis 31 is inclined in relation to the axis 25_1 of the hole." (EX1006, ¶27).





(EX1007, Fig. 4; EX1006, Fig. 4).

249. Mr. Sherman overlooks Arnould's disclosure that "[t]he plate 1 depicted is the most appropriate for the patient, particularly for the size of his metatarsal M and phalanx P." (*Id.*, ¶12). Nowhere does Mr. Sherman discuss how the dimensions of Zahiri's odd angle internal fixation device "for use in a transverse fracture of a humerus" would be modified for a plate that is placed "on the upper

surfaces of the metatarsal and phalanx connected by the joint." (EX1007, Title; EX1006, ¶8).

250. As discussed above, Arnould teaches away from Zahiri. Combining Zahiri with Arnould would take away important advantages of Arnould, namely, a design specifically contoured for a metatarsophalangeal joint, and a surgeon's ability to contour and adapt the Arnould plate according to a desired dorsiflexion angle.

3. Mr. Sherman's Combination is Based on Hindsight

251. Further, Mr. Sherman purports to incorporate the temporary guide pins of Zahiri into Arnould's plate. (EX1002, ¶¶252-256). Mr. Sherman concedes that "Arnould lack[s] [sic] sufficient disclosure regarding the use of temporary fixation members in the guide holes." (*Id.*, ¶252). This appears to be based on hindsight reasoning.

252. Regarding Zahiri, and as discussed above in Section XI.A.3., the "pin holes" and "four tips" of Zahiri were a specific improvement to the '055 patent and were included to solve the problem of torqueing, or spinning of the guide plate on the humeral cortex as the lag screw was advanced into the epiphysis. (EX2010, Fig. 3, EX1007, Fig. 3, 1:55-61, 3:41-44, 5:52-59). With the guide plate of the '055 patent having a smooth surface and having only one fixation screw—the lag screw, additional fixation was required for Zahiri.

253. In my opinion, a POSITA would not have been motivated to combine

Arnould and Zahiri because the pre-existing screw holes of Arnould would have been used to position the bone plate prior to inserting the cross screw, thereby eliminating the need to incorporate the temporary fixation features of Zahiri. (EX2007, ¶¶43-45, 63-66)).

254. For example, Arnould's plate expressly describes using screw 2 and oblong hole 16 to "partially immobilize" the plate body 10 until the screw 2 is later "completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the metatarsal M." (EX1006, ¶¶31-33, 8). Indeed, Arnould's disclosed method "for placing a metatarsal-phalangeal joint arthrodesis plate" requires, amongst other steps, first "[p]artially immobilizing the plate body on the metatarsal, allowing relative freedom of movement generally along the longitudinal direction of the plate body" and then "[p]ermanently immobilizing the plate body on the metatarsal and phalanx." (*Id.*).

255. Moreover, Arnould's plate is not at risk for the unwanted torquing or spinning of the guide plates disclosed in the '055 patent and Zahiri because (1) Arnould's plate is contoured to the metatarsal and phalanx, with a leg wrapping around the phalangeal epiphysis, and (2) Arnould may be "partially immobilized" by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M. (*Id.*, ¶31). As such, a POSITA would understand that proper

alignment and temporary fixation is obtained in Arnould without the need for the separate "temporary guide pins used with pin holes" of Zahiri.[2] Therefore, a POSITA would not have been motivated to combine Zahiri with Arnould.

4. No Reasonable Expectation of Success In Combining Arnould and Zahiri

256. Mr. Sherman's "Basis for Combination" and element-by-element analysis of the challenged claims does not comment on whether a POSITA would have had a reasonable expectation of success in combining Arnould with Zahiri. For example, Mr. Sherman simply states that "a POSITA would have readily looked to Zahiri for a way to provide better compression across the joint because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture." (EX1002, ¶265, *see also id.*, ¶280). This is not a sufficient rationale to support a reasonable expectation of success in combining Zahiri with Arnould.

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[2] Mr. Sherman selectively combines only the "temporary guide pins used with pin holes" of Zahiri with Arnould while failing to address or include the added fixation of the four tips of Zahiri. (EX1002, ¶¶250-256). Adding the four tips of Zahiri to Arnould's plate would not allow the plate body 10 to remain "displaceable in the direction 11 relative to the metatarsal M." (EX1006, ¶¶31-33). This displacement is made possible by screw 2 and oblong hole 16 when the plate is temporarily fixed to the bones. (*Id.*).

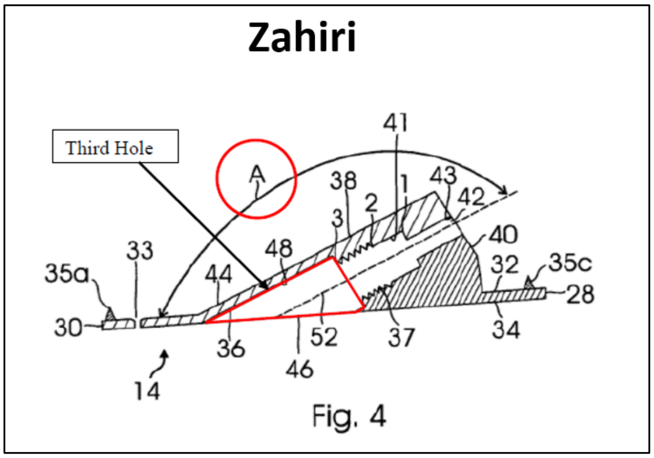
257. First, Mr. Sherman does not explain how Zahiri allegedly provides "better compression across a joint." Indeed, since Zahiri is not even directed to arthrodesis, Zahiri indisputably does not provide a way to provide better compression across a joint. (EX1007, 2:16-19; EX2009, 134:14-19). Mr. Sherman also fails to explain why providing better compression is relevant or even related to a hole being "angled relative to the longitudinal axis of said bone plate."

258. Second, Mr. Sherman's reason to combine, i.e., "because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture," does not explain why a POSITA would have had a reasonable expectation of success in combining Zahiri with Arnould. Contrary to Mr. Sherman's broad statement, a POSITA would have recognized that while some bone plates may be used for joint fusion and fracture fixation, this does not mean that every bone plate for fracture fixation necessarily can be interchanged with every bone plate for joint fusion. Here, as explained above, Zahiri does not even disclose a bone plate and its precise guiding function differs substantially from the Arnould bone plate, which allows the surgeon the option to conform the Arnould plate to a patient's anatomy and to select the trajectory of the cross-joint screw. Mr. Sherman even concedes that Zahiri is "not focused at arthrodesis." (*Id.*, 134:14-19).

5. Mr. Sherman Does Not Provide a Motivation to Combine the Embodiments of Zahiri

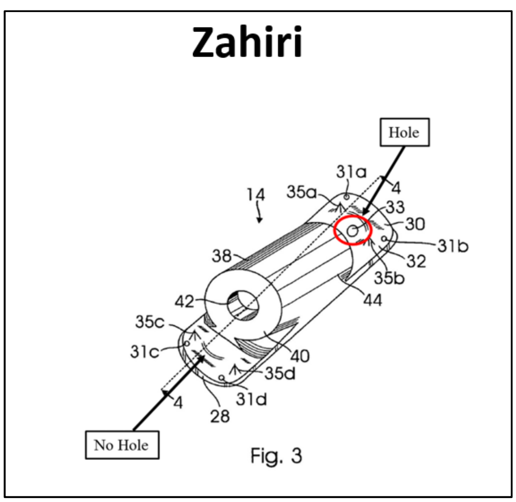
259. Furthermore, in my opinion, Mr. Sherman relies on different

embodiments in Zahiri to show multiple claim limitations of the 751 patent. For example, in claim 1, Mr. Sherman provides annotations on Zahiri Figure 4 with labels for "Third Hole" in an attempt to demonstrate that Zahiri's alleged "third hole" is "located between said first hole and said second hole,"



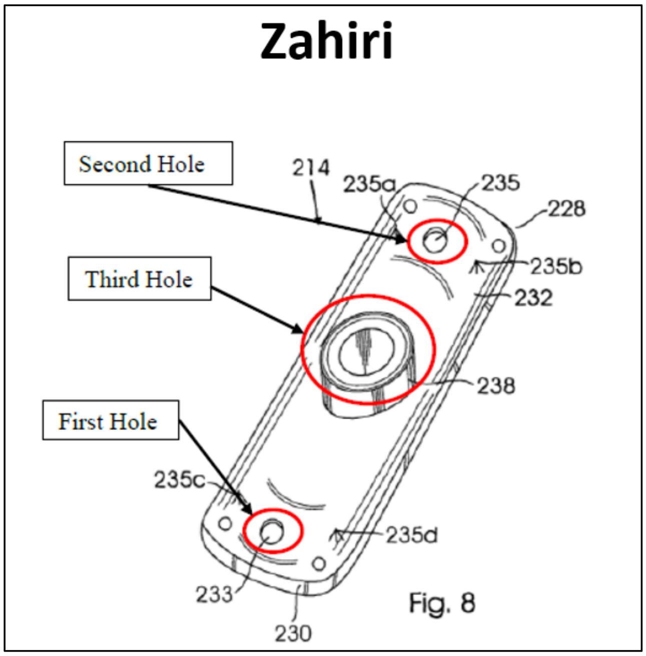
(EX1002, ¶264).

260. But the device shown in Figure 4 (also shown in Figure 3 below) does not disclose an alleged "second hole."



(EX1007, Fig. 3).

261. Mr. Sherman then provides annotations on Zahiri Figure 8 with a label for "Second Hole." (EX1002, ¶267). Also present are labels for the "First Hole" and "Third Hole." (*Id.*).



(*Id.*)

262. Zahiri, however, discloses that "the device 20 [shown in Figures 7 and 8] is different from that of 10 [shown in figures 1-4]. The difference includes the barrel portion and two additional screws." (EX1007, 8:32-34). Additionally, Mr. Sherman confirmed that Zahiri discloses multiple embodiments. (EX2009, 88:24-89:3 ("Q. . . . Would you agree with me that the [Zahiri] figures depict several different embodiments? . . . A. I think that's correct.")). As such, it is my opinion

that Mr. Sherman relies on the multiple embodiments of Zahiri in arriving at the claimed invention.

263. Notably, Mr. Sherman's declaration does not provide a motivation to combine the different embodiments of Zahiri. He does not discuss whether a POSITA would have had a reasonable expectation of success in combining the different embodiments of Zahiri.

264. For the reasons explained above, a POSITA would not have been motivated to combine Arnould and Zahiri. Thus, Arnould and Zahiri do not render obvious the challenged claims.

B. Arnould and Zahiri Do Not Render Obvious Independent Claims 1, 11, and 17

1. Claim 1

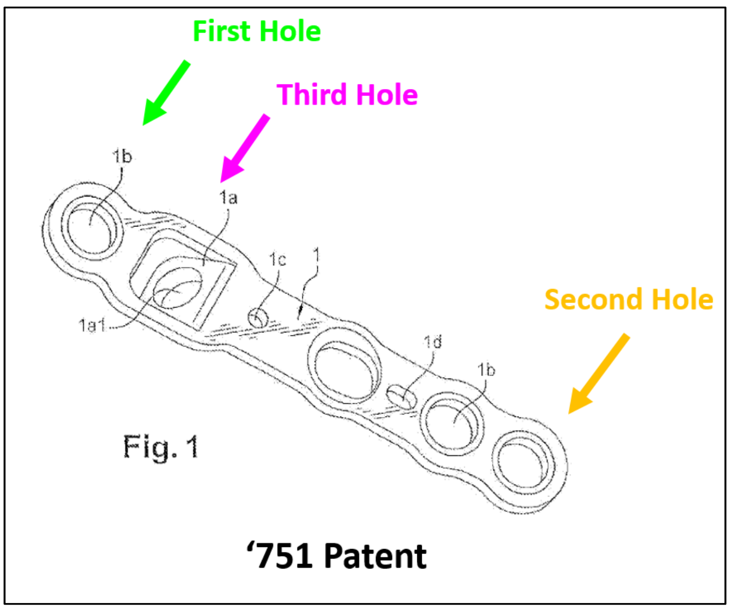
265. I have analyzed Petitioner and Mr. Sherman's opinion that Arnould and Zahiri render obvious claim 1. In my opinion, Arnould and Zahiri do not render obvious claim 1 of the 751 patent.

a. [1d-1] "A Third Hole Located Between Said First Hole And Said Second Hole"

266. To show that Arnould discloses "a third hole located between said first hole and said second hole," Mr. Sherman simply cites to Figure 2 of Arnould without any explanation or annotation. (EX1002, ¶264). It appears that Mr. Sherman assumes that hole 25 of leg 20 of Arnould is "between said first hole and said second

hole." (*Id.*). I disagree.

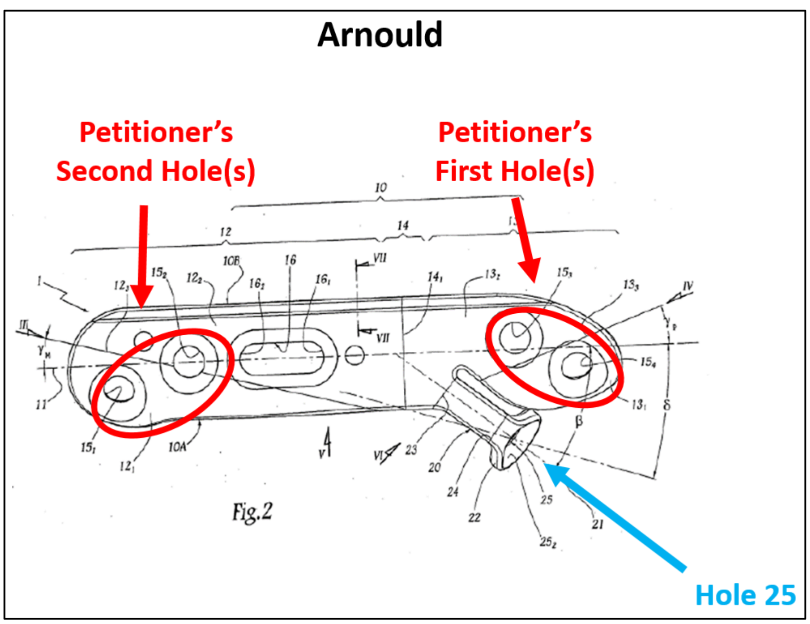
267. As discussed *supra* in Section V.C., the claim term "between" from independent claims 1, 11, and 17 means "at, into, or across the space separating two objects, places, or points." (EX2015). For example, as shown below in Figure 1 of the 751 patent, use of the term "between," such as "a third hole located ***between*** said first hole and said second hole," refers to the third hole located in the space separating the first hole and the second hole.



(EX1001, Fig. 1, cls. 1, 11, 17).

268. As shown in annotated Figure 2 below, Mr. Sherman identifies hole 25 of Arnould as the "third hole." Hole 25 is located on leg 20, which "extends lengthwise from the phalangeal portion 13" and "gives the impression of plunging downward in relation to the plate body 10, so that its end 22, which is located

vertically below this plate body in the configuration of implantation of the plate 1, is pressed against the inner lateral surface of the phalangeal epiphysis P1." (EX1006, ¶¶23, 26). In addition, the longitudinal direction 21 of leg 20 extends at an angle β from the longitudinal direction 11 of the plate body 10. (*Id.*, ¶25). As compared to holes 15_3 and 15_4 (identified by Mr. Sherman as the "first hole(s)") and holes 15_1 and 15_2 (identified by Petitioner as the "second hole(s)," hole 25 is not "between" the first hole and the second hole as claimed. (EX1001, cl. 1). A POSITA would understand the claim term "between the first and second hole" as referring to the space separating the first hole and the second hole. (*Id.*, Fig. 2; EX2015). Moreover, if leg 20 is straightened, hole 25 appears to be positioned beyond first hole 15_3 and possibly beyond at least a portion of first hole 15_4 rather than between any first hole and second hole.



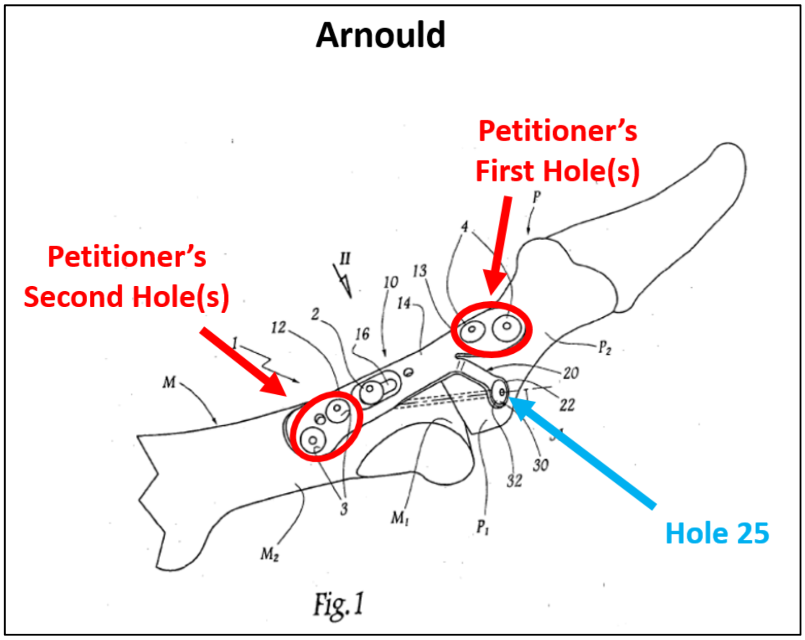


Fig. 1

(EX1006, Fig. 1, Fig. 2). As shown in annotated Figures 1 and 2, hole 25 of Arnould is not located in the space separating the "first hole" and "second hole" but is rather located below, off to the side of, and on a different plane as compared with the first and second holes.

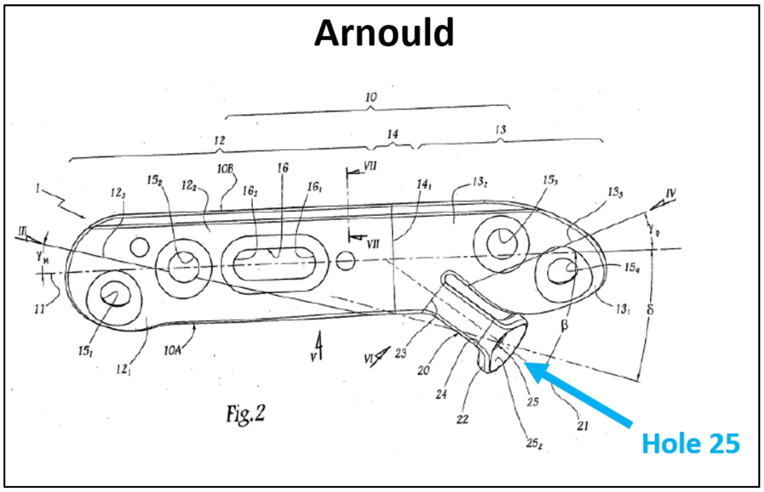
269. Thus, Arnould and Zahiri do not render obvious claim 1.

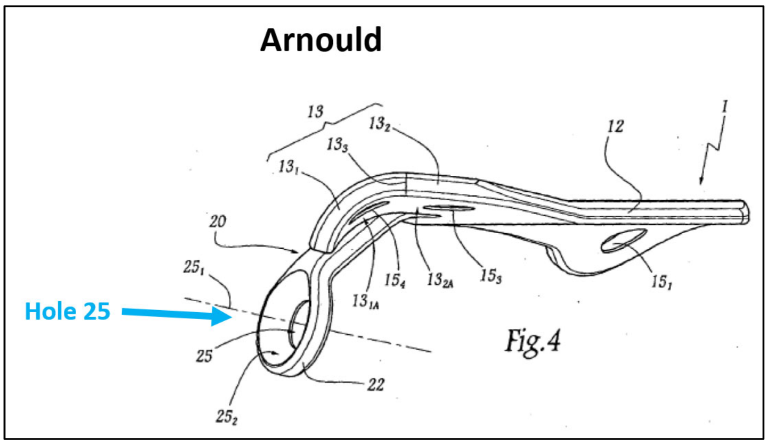
b. [1d-2] "Said Third Hole Is Angled Relative To The Longitudinal Axis Of Said Bone Plate"

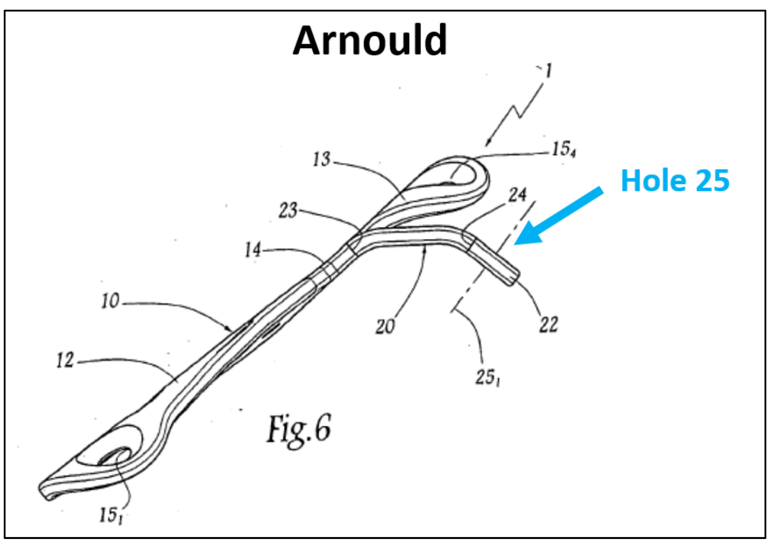
270. With respect to Arnould, Mr. Sherman opines that "the trajectory of screw 30, and therefore the hole itself, is angled relative to the longitudinal axis of the plate. (δ)." (EX1002, ¶263). In his view, "the hole 25 is connected to leg 20, where leg 20 is offset at angle β with respect to the longitudinal axis of the plate. (EX1006 at ¶25)." (*Id.*). I disagree.

271. Angle β is formed by the longitudinal direction 11 and longitudinal direction 21 of leg 20 (which is part of the plate), not hole 25. (EX1006, ¶25 ("***the leg 20*** is inclined in relation to the plate body 10: ***its longitudinal direction 21 forms a non-zero angle β with the longitudinal direction 11 of the plate body***." (emphasis added)). Similarly, while the trajectory of screw 30 may be angled, it does not follow that hole 25 itself is necessarily angled. Rather, the size and shape of the screw head may permit the screw to be placed at different trajectories regardless of whether the hole is angled. For example, a bone screw with a diameter smaller than the diameter of the hole may enable variable angles of fixation. Other factors such as the shape of the screw head and the material or geometric shape or design of the plate may also affect screw trajectory.

272. Moreover, hole 25 is not an "angled hole" as claimed. Rather, hole 25 appears to have the same shape and geometry of holes 15_1, 15_2, 15_3, and 15_4, none of which are angled through the bone plate. (*Id.*, Figs. 2, 4, 6). Hole 25 includes "a concave surface which is substantially complementary to an associated surface delimited by this screw head." (*Id.*, ¶27). As can been seen in Figures 2, 4, and 6 below, holes 15_1, 15_2, 15_3, and 15_4 depict the same concave surface as 25_2 of hole 25 and the same circular shape as hole 25.


Arnould
Fig.2
Hole 25


Arnould
Hole 25
Fig.4


Arnould
Hole 25
Fig.6

(*Id.*, Fig. 2, Fig. 4, Fig. 6).

273. Before the Arnould plate is bent to contour to the metatarsophalangeal joint, Arnould describes that the plate "is manufactured from a flat metal plate." (*Id.* at ¶39). Aside of the chamfered edge (17), plate body 10, which includes holes 15_1, 15_2, 15_3, 15_4, and 25 disposed therein, has a uniform thickness. (*Id.*, *see also id.*, Fig. 7). Arnould nowhere states or shows that hole 25 is angled through the thickness of the plate.

274. Mr. Sherman also states that "[t]o the extent that Arnould is found to not explicitly disclose this element, a POSITA would have readily looked to Zahiri for a way to provide better compression across the joint because there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture." (EX1002, ¶265). First, as I explained above, a POSITA would not have been motivated to combine Arnould and Zahiri and Mr. Sherman provides no reasoning for such combination. (*see supra* at Section XIII.A.). As I explained above, a POSITA would understand that Arnould actually teaches away from Zahiri. (*Id.*). Specifically, Mr. Sherman provides no reasoning or justification for his statement that Zahiri could allegedly "provide better compression across the joint", much less does he provide any explanation of whether a POSITA would have a reasonable expectation of success in making such a combination.

275. Thus, Arnould and Zahiri do not render obvious claim 1.

2. Claim 11

276. I have analyzed Petitioner and Mr. Sherman's opinion that Arnould and Zahiri render obvious claim 11. In my opinion, Arnould and Zahiri do not render obvious claim 11 of the 751 patent.

a. [11d] "A Third Hole and A Fourth Hole Located Between The First Hole and The Second Hole"

277. For the reasons discussed above with respect to claim 1 of Ground 4, claim 11 must fail because Arnould does not disclose "a third hole and a fourth hole located between the first hole and the second hole." (Section XIII.B.1). Mr. Sherman relies solely on Zahiri for this limitation, stating that "Arnould is silent regarding the dimensions of hole 25." (EX1002, ¶286). For the reasons discussed above in Section XIII.A., a POSITA would not have been motivated to combine the alleged "third hole and fourth hole" of Zahiri with Arnould. As such, Arnould and Zahiri do not render obvious claim 11 of the 751 patent.

278. Mr. Sherman states that "Zahiri discloses this claim element," citing to Section VIII.B.3.v, Mr. Sherman's earlier analysis of "[11d] a third hole" for Ground 2 based on **Slater and Zahiri**. (*Id.*, ¶287). Like its Ground 2 analysis, Mr. Sherman simply states: "a POSITA looking for a way to improve the integrity of the angled fixation screw of Arnould's bone plate, would have readily looked to the disclosure of Zahiri to implement this improvement." (*Id*). Mr. Sherman does not explain ***why***

a POSITA would need to "improve the integrity of the angled fixation screw," ***why*** a POSITA would specifically look to Zahiri, and ***whether*** a POSITA would have a reasonable expectation of success in making such combination. Moreover, Mr. Sherman does not explain why he relies on an alleged motivation to combine rationale for Slater with Zahiri to support a motivation to combine Arnould with Zahiri.

b. [11h] "A Third Fixation Member Configured To Be Inserted Through The Third Hole and Fourth Hole"

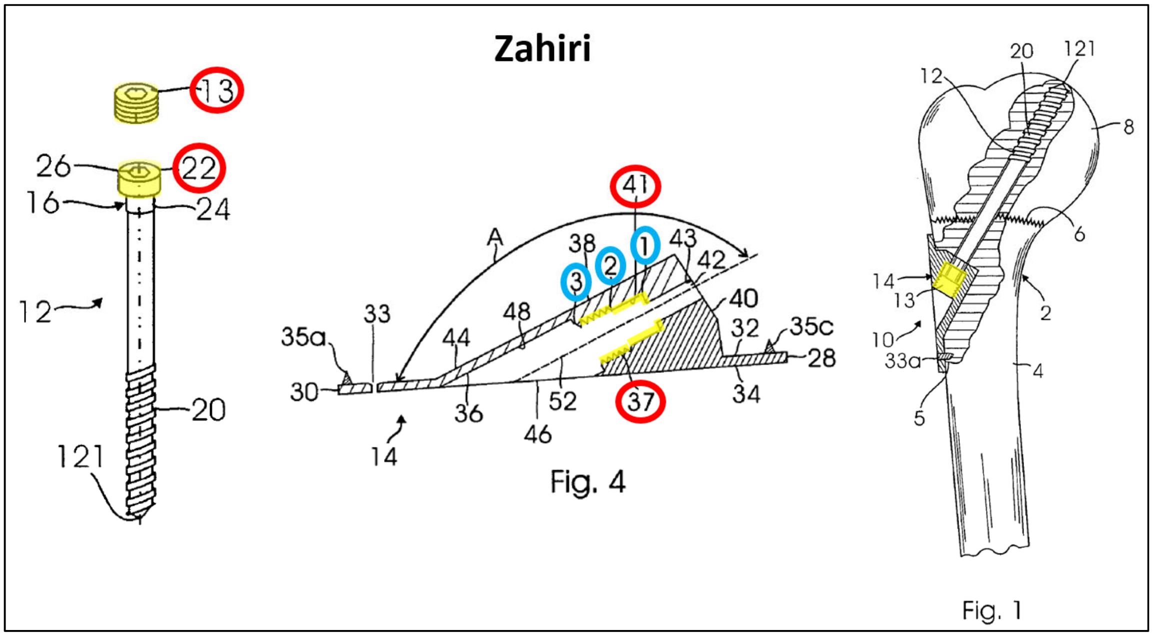
279. With respect to "a third fixation member configured to be inserted through the third and fourth hole," Mr. Sherman relies on the lag screw of Zahiri that perfectly mates with the strict geometry of barrel portion 38. (*Id.*, ¶¶294-296). Mr. Sherman concedes that Arnould "lacks sufficient disclosure of the third fixation member being inserted through a third and fourth hole where the fourth hole is smaller than the third hole." (*Id.*, ¶294). To support the alleged deficiency, Mr. Sherman posits that "a POSITA would look to relevant prior art like Zahiri for disclosure of a fixation member used in such a configuration" and "would be motivated to combine the teachings of Arnould and Zahiri to further improve the integrity of the angled fixation screw of Arnould's bone plate by utilizing the disclosure of the lag screw from Zahiri." (*Id.*, ¶¶294, 298). I disagree.

280. As explained above in Section XIII.A.2, incorporating Zahiri's barrel

portion into Arnould takes away the ability to select multiple trajectories for screw 30 of Arnould. Mr. Sherman fails to explain whether a POSITA would have had a reasonable expectation of success in making such a combination. In my opinion, a POSITA would understand that Zahiri's locking screw/lag screw arrangement would not fit in the thin, pliable, metatarsophalangeal plate of Arnould.

281. For example, as discussed above, the barrel portion of Zahiri is defined by a series of walls that make up the "cylindrical hollow structure," including, opening side wall 42, inner cylindrical wall 41, threaded side wall portion 37, and inner side wall 48. (EX1007, 6:14-18). Inner cylindrical wall 41 and threaded side wall portion 37 include specific lengths "defined between the first point 1 and the second point 2," and "the second point 2 to a third point 3," respectively. (*Id.*, 6:18-24). For inner cylinder wall 41, the length between the first point 1 and the second point 2 is equal to "the height of the proximal head 22 of the lag screw 12." (*Id.*) For threaded side wall portion 37, the length between the second point 2 to a third point 3 is slightly less than "the height of the locking screw 13." (*Id.*). Of course, the size and lengths of the walls of Zahiri's barrel portion, as well as the lag screw and locking screw, are all relative to a proximal humerus—a bone much larger than both the tibia and the talus. (*Id.*, Abstract ("The present invention is an improved unique odd angle internal fixation device for both a transverse fracture and longitudinal fracture located at the junction of the metaphysis and diaphysis of a long

bone such as the proximal humerus.”)).



(*Id.*, Fig. 1, Fig. 2, Fig. 4).

282. Integrating the dimensions of inner cylindrical wall 41 and threaded side wall portion 37 into the Arnould plate would not “improve the integrity of the angled fixation screw of Arnould’s bone plate” because the Arnould plate is not designed to account for such depth at the metatarsophalangeal joint. Moreover, including the length, size, and diameters of inner side wall 48 and the opening side wall 43 would require even more space in the Arnould plate, and in the metatarsophalangeal joint, to accommodate these additional structures.

283. At his deposition, Mr. Sherman was asked how a person of ordinary skill in the art would understand Zahiri’s size in comparison to the humerus bone

shown in Figure 1. In response, Mr. Sherman stated that "a person of ordinary skill in the art would look at that figure and appreciate, you know, the scale of the plate relative to the proximal end of the humerus." (EX2009, 98:3-5). I agree with Mr. Sherman that Zahiri's barrel portion, lag screw, and locking screw are specifically sized to fit into the large, bulbous proximal end of the humerus. In contrast, the Arnould plate is designed "for a metatarsophalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe." (EX1006, ¶1). In particular, the Arnould "plate 1 depicted is the most appropriate one for the patient, particularly for the size of his metatarsal M and phalanx P." (*Id.*, ¶12). And of course, the Arnould plate is shaped and contoured to the metatarsophalangeal joint. (*Id.*, *see also id.*, Fig. 1, Fig. 2, Fig. 4, Fig. 6). As discussed above, including Zahiri's locking screw on top of the lag screw would require that leg 20 of Arnould be even larger and more prominently protruding from the surface of the bone plate. (Section XIII.A.2). As such, a POSITA would not "improve the integrity of the angled fixation screw of Arnould's bone plate by utilizing the disclosure of the lag screw from Zahiri." (EX1002, ¶295).

284. Thus, Arnould and Zahiri do not render obvious claim 11.

c. [11e] "A Fifth Hole" and [11i] "A Temporary Fixation Member Configured to Be Inserted Through the Fifth Hole"

285. As discussed above, a POSITA would not have been motivated to

combine Arnould and Zahiri because the pre-existing screw 2 and oblong hole 16 of Arnould would have been used to partially immobilize the bone plate prior to insertion of the cross-joint screw, thereby eliminating the need to incorporate the "fifth hole" and "temporary fixation member configured to be inserted ***through the fifth hole***" of Zahiri. (EX2007, ¶¶43-45, 63-66; Section XIII.A.3.). As such, Slater and Zahiri do not render obvious "a fifth hole located adjacent either the first hole or the second hole, said fifth hole being smaller in area than said first hole or said second hole" and "a temporary fixation member configured to be inserted through the fifth hole in the bone plate."

286. In addition, Mr. Sherman relies on the different embodiments shown in Figures 2 and 8 of Zahiri in an attempt to meet claim 11. (EX1002, ¶290). Mr. Sherman does not provide an opinion as to why a POSITA would be motivated to combine the different embodiments shown in Figures 2 and 8 in arriving at claim 11. Mr. Sherman also does not explain why a POSITA would have had a reasonable expectation of success in making the alleged combination.

287. Thus, Arnould and Zahiri do not render obvious claim 11.

3. Claim 17

288. I have analyzed Petitioner and Mr. Sherman's opinion that Arnould and Zahiri render obvious claim 17. In my opinion, Arnould and Zahiri do not render obvious claim 17 of the 751 patent.

a. [17d-1] "A Third Hole Located Between Said First Hole and Said Second Hole."

289. For the reasons discussed above with respect to claim 1 of Ground 4, claim 17 must fail because Arnould does not disclose "a third hole located between said first hole and said second hole." (Section XIII.B.1). Moreover, for the reasons discussed above in Section XIII.A., a POSITA would not have been motivated to combine Zahiri with Arnould. As such, Arnould and Zahiri do not render obvious claim 17 of the 751 patent.

b. [17d-2] "Said Third Hole Being Angled Relative to Said Bone Plate"

290. For the reasons discussed above with respect to claim 1 of Ground 4, Arnould does not disclose "said third hole being angled relative to said bone plate." (Section XIII.B.1). Moreover, for the reasons discussed above, a POSITA would not have been motivated to combine Zahiri with Arnould. As such, Arnould and Zahiri do not render obvious claim 17 of the 751 patent.

c. [17e] "A Pin Hole"

291. As discussed above, a POSITA would not have been motivated to combine Arnould and Zahiri because the pre-existing screw 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the bone plate to the joint, thereby eliminating the need to incorporate the "pin hole" of Zahiri. (EX2007, ¶¶43-45, 63-66). As such, Arnould and Zahiri do not render obvious "a pin hole located

adjacent either said first hole or said second hole."

292. For this limitation, Mr. Sherman provides a cross reference to a completely different claim limitation without reconciling the differences in claim language. (EX1002, ¶321 ("[17i] a pin hole located . . ." referring to Section VIII.D.3.vi "[11e] a fifth hole" at 130)). To the extent that Mr. Sherman equates the "pin hole" of claim 17 with the "fifth hole" of claim 11, Mr. Sherman does not explain his opinion and as a result, provides an insufficient obviousness analysis for claim 17.

293. Following Mr. Sherman's internal cross reference, and assuming the "fifth hole" of claim 11 is the same as the "pin hole" of claim 17, Mr. Sherman relies solely on Zahiri for claim 17 because "Arnould is silent regarding the use of temporary fixation members." (*Id.*, ¶289). As such, for claim 17, Mr. Sherman necessarily relies on the assertion that "[a] POSITA would look to relevant prior art like Zahiri for disclosure of temporary fixation members known in the art." (*Id.*). As discussed above in Section XIII.A.3, a POSITA would understand that the pre-existing screw 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the bone plate prior to insertion of the cross-joint screw, thereby eliminating the need to incorporate Zahiri's temporary fixation features. (EX2007, ¶¶43-45, 63-66). As such, a POSITA would not have been motivated to combine Arnould with Zahiri in arriving at claim 17.

294. In addition, Mr. Sherman relies on the different embodiments shown in Figures 2 and 8 of Zahiri in an attempt to meet claim 17. (EX1002, ¶321). Mr. Sherman does not provide an opinion as to why a POSITA would be motivated to combine the different embodiments shown in Figures 2 and 8 in arriving at claim 17. Mr. Sherman also does not explain why a POSITA would have had a reasonable expectation of success in making the alleged combination.

295. Thus, Arnould and Zahiri do not render obvious claim 17

C. Arnould and Zahiri Do Not Render Obvious Dependent Claims 2-3, 7-10, 12-16, and 18

296. Claims 2, 3, and 7-10 depend on claim 1, claims 12-16 depend on claim 11, and claim 18 depends on claim 17. Because Arnould and Zahiri do not render obvious claims 1, 11, and 17 of the '751 patent, Arnould and Zahiri do not render obvious claims 2, 3, 7-10, 12-16, or 18 either.

1. Claims 2 and 12

297. ***Dependent claims 2 and 12*** recite "wherein said bone plate is contoured to anatomically fit bones in a human foot." Arnould and Zahiri do not render obvious claims 1 and 11, as discussed above. Because Arnould and Zahiri do not render obvious claims 1 and 11 of the 751 patent, Arnould and Zahiri do not render obvious claims 2 and 12 either.

2. Claim 3

298. ***Dependent claim 3*** recites "[t]he system of claim 1 wherein said joint

is a metatarsophalangeal joint." Arnould and Zahiri do not render obvious claim 1, as discussed above. Because Arnould and Zahiri do not render obvious claim 1 of the 751 patent, Arnould and Zahiri do not render obvious claim 3 either.

3. Claim 7

299. ***Dependent claim 7*** recites "[t]he system of claim 1 wherein said third fixation member is configured to develop compression across said joint with lag effect when said third fixation member is tightened." Arnould and Zahiri do not render obvious claim 1, as discussed above. Because Arnould and Zahiri do not render obvious claim 1 of the 751 patent, Arnould and Zahiri do not render obvious claim 7 either.

4. Claims 8 and 13

300. ***Dependent claim*s *8 and 13*** recite "wherein the free end of said third fixation member and a free end of said second fixation member are configured to reside adjacent each other within said second discrete bone." Arnould and Zahiri do not render obvious claims 1 and 11, as discussed above. Because Arnould and Zahiri do not render obvious claims 1 and 11 of the 751 patent, Arnould and Zahiri do not render obvious claims 8 and 13 either.

5. Claim 9

301. ***Dependent claim 9*** recites "[t]he system of claim 1 wherein said bone plate includes at least one pin hole adjacent said first hole, said pin hole configured

to receive a temporary fixation member." Arnould and Zahiri do not render obvious claim 1, as discussed above. In my opinion, Arnould and Zahiri do not render obvious claim 9.

302. As discussed above, a POSITA would not have been motivated to combine Arnould and Zahiri because the pre-existing screw 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the plate prior to insertion of the cross-joint screw, thereby eliminating the need to incorporate the "pin hole" of Zahiri. (EX2007, ¶¶43-45, 63-66). As such, Arnould and Zahiri do not render obvious "[t]he system of claim 1 wherein said bone plate includes at least one pin hole adjacent said first hole, said pin hole configured to receive a temporary fixation member."

303. Additionally, Mr. Sherman provides a cross reference to a different claim limitation without explaining the differences in claim language. (EX1002, ¶332 ("Claim 9" referring to Section VIII.D.3.vi ("[11e] a fifth hole") at 130 and Section VIII.D.3.xii. ("[11k] and a temporary fixation member") at 134)). To the extent that Mr. Sherman equates the "pin hole" of claim 9 with the "fifth hole" of claim 11, Mr. Sherman does not explain his opinion and as a result, provides an insufficient obviousness analysis for claim 9.

304. Following Mr. Sherman's internal cross reference, and assuming the "fifth hole" is the same as the "pin hole" of claim 9, Mr. Sherman relies solely on

Zahiri for claim 9 because "Arnould is silent regarding the use of temporary fixation members with the guide holes shown in its figures." (*Id.*, ¶289). As such, for claim 9, Mr. Sherman necessarily relies on the assertion that "[a] POSITA would look to relevant prior art like Zahiri for disclosure of temporary fixation members known in the art." (*Id.*). As discussed above, a POSITA would not have been motivated to combine Arnould with Zahiri in arriving at claim 9.

305. In addition, Mr. Sherman relies on the different embodiments shown in Figures 2 and 8 of Zahiri in an attempt to meet claim 9. (EX1002, ¶332 ("a POSITA would find this claim obvious in view of Arnould and Zahiri (*See* EX1007, **FIGS. 2, 8**, 5:47:64, 3:10-18, 7:63-8:11)." (emphasis added)). Mr. Sherman does not provide an opinion as to why a POSITA would be motivated to combine the different embodiments shown in Figures 2 and 8 in arriving at claim 9. Mr. Sherman also does not explain why a POSITA would have had a reasonable expectation of success in making the alleged combination.

306. Thus, Arnould and Zahiri do not render obvious claim 9.

6. Claim 10

307. ***Dependent claim 10*** recites "[t]he system of claim 1 wherein said bone plate includes at least one pin hole adjacent said second hole, said pin hole configured to receive a temporary fixation member." Arnould and Zahiri do not render obvious claim 1, as discussed above. In my opinion, Arnould and Zahiri do

not render obvious claim 10.

308. As discussed above, a POSITA would not have been motivated to combine Arnould and Zahiri because the pre-existing screw hole 2 and oblong hole 16 of Arnould would have been used to ”partially immobilize” the bone plate prior to insertion of the cross-joint screw, thereby eliminating the need to incorporate the “pin hole” of Zahiri. (EX2007, ¶¶43-45, 63-66). As such, Arnould and Zahiri do not render obvious “[t]he system of claim 1 wherein said bone plate includes at least one pin hole adjacent said second hole, said pin hole configured to receive a temporary fixation member.”

309. Additionally, Mr. Sherman provides a cross reference to a different claim limitation without explaining the differences in claim language. (EX1002, ¶33 (“Claim 9” referring to Section VIII.D.3.vi (“[11e] a fifth hole”) at 130 and Section VIII.D.3.xii. (“[11k] and a temporary fixation member”) at 134)). To the extent that Mr. Sherman equates the “pin hole” of claim 10 with the “fifth hole” of claim 11, Mr. Sherman does not explain his opinion and as a result, provides an insufficient obviousness analysis for claim 10.

310. Following Mr. Sherman’s internal cross reference, and assuming the “fifth hole” is the same as the “pin hole” of claim 10, Mr. Sherman relies solely on Zahiri for claim 10 because “Arnould is silent regarding the use of temporary fixation members with the guide holes shown in its figures.” (*Id.*, ¶289). As such,

for claim 10, Mr. Sherman necessarily relies on the assertion that "[a] POSITA would look to relevant prior art like Zahiri for disclosure of temporary fixation members known in the art." (*Id.*). As discussed above, a POSITA would not have been motivated to combine Arnould with Zahiri in arriving at claim 10.

311. In addition, Mr. Sherman relies on the different embodiments shown in Figures 2 and 8 of Zahiri in an attempt to meet claim 10. (EX1002, ¶333 ("a POSITA would find this claim obvious in view of Arnould and Zahiri (*See* EX1007, **FIGS. 2, 8**, 5:47:64, 3:10-18, 7:63-8:11)." (emphasis added)). Mr. Sherman does not provide an opinion as to why a POSITA would be motivated to combine the different embodiments shown in Figures 2 and 8 in arriving at claim 10. Mr. Sherman also does not explain why a POSITA would have had a reasonable expectation of success in making the alleged combination.

312. Thus, Arnould and Zahiri do not render obvious claim 10.

7. Claim 14

313. ***Dependent claim 14*** recites "[t]he system of claim 11 wherein the bone plate is substantially planar." Arnould and Zahiri do not render obvious claim 11, as discussed above. Because Arnould and Zahiri do not render obvious claim 11 of the 751 patent, Arnould and Zahiri do not render obvious claim 14 either.

8. Claim 15

314. ***Dependent claim 15*** recites "[t]he system of claim 11 wherein the fifth

hole is a pin hole." Arnould and Zahiri do not render obvious claim 11, as discussed above. In my opinion, Arnould and Zahiri do not render obvious claim 15.

315. As discussed above, a POSITA would not have been motivated to combine Arnould and Zahiri because the pre-existing screw hole 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the bone plate prior to insertion of the cross-joint screw, thereby eliminating the need to incorporate the "fifth hole" of Zahiri. (EX2007, ¶¶43-45, 63-66). As such, Arnould and Zahiri do not render obvious "[t]he system of claim 15 wherein the fifth hole is a pin hole."

316. Following Mr. Sherman's internal cross reference to Section VIII.D.3.vi ("[11e] a fifth hole") at 130, Mr. Sherman relies solely on Zahiri for claim 15 because "Arnould is silent regarding the use of temporary fixation members with the guide holes shown in its figures." (*Id.*, ¶289). As such, for claim 15, Mr. Sherman necessarily relies on the assertion that "[a] POSITA would look to relevant prior art like Zahiri for disclosure of temporary fixation members known in the art." (*Id.*). As discussed above, a POSITA would not have been motivated to combine Arnould with Zahiri in arriving at claim 15.

317. In addition, Mr. Sherman relies on the different embodiments shown in Figures 2 and 8 of Zahiri in an attempt to meet claim 15. (EX1002, ¶338 ("a POSITA would find this claim obvious in view of Arnould and Zahiri (*See* EX1007, **FIGS. 2, 8**, 5:47:64, 3:10-18)." (emphasis added)). Mr. Sherman does not provide an

opinion as to why a POSITA would be motivated to combine the different embodiments shown in Figures 2 and 8 in arriving at claim 15. Mr. Sherman also does not explain why a POSITA would have had a reasonable expectation of success in making the alleged combination.

318. Thus, Arnould and Zahiri do not render obvious claim 15.

9. Claims 16 and 18

319. ***Dependent claim 16*** recites "wherein the temporary fixation member is a guide pin" and ***dependent claim 18*** recites "wherein the temporary fixation is a guide pin." Arnould and Zahiri do not render obvious claims 11 and 17, as discussed above. In my opinion, Arnould and Zahiri do not render obvious claims 16 and 18.

320. As discussed above, a POSITA would not have been motivated to combine Arnould and Zahiri because pre-existing screw hole 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the bone plate prior to inserting the cross-joint screw, thereby eliminating the need to incorporate the "temporary fixation member" or "guide pin" of Zahiri. (EX2007, ¶¶43-45, 63-66). As such, Arnould and Zahiri do not render obvious "[t]he system of claim 11 wherein the temporary fixation member is a guide pin" and "[t]he orthopedic implant of claim 17 wherein the temporary fixation is a guide pin."

321. Following Mr. Sherman's internal cross reference to Section VIII.D.3.xii ("[11k] and a temporary fixation member") at 134, Mr. Sherman relies

solely on Zahiri for claims 16 and 18 because "Arnould is silent regarding the use of temporary fixation members with the guide holes shown in its figures." (*Id.*, ¶303). As such, for claims 16 and 18, Mr. Sherman necessarily relies on the assertion that "[a] POSITA would look to relevant prior art like Zahiri for disclosure of temporary fixation members known in the art." (*Id.*). As discussed above, a POSITA would not have been motivated to combine Arnould with Zahiri in arriving at claims 16 and 18.

322. Arnould and Zahiri do not render obvious claims 16 and 18.

XIV. GROUND 5: ARNOULD, ZAHIRI, AND MYERSON DO NOT RENDER OBVIOUS CLAIM 6

323. In my opinion, Arnould, Zahiri, and Myerson do not render obvious claim 6 the 751 patent.

A. Mr. Sherman Does Not Articulate a Motivation to Combine Arnould, Zahiri, and Myerson

324. Paragraphs 343 and 344 of the Sherman Declaration are directed to the "MTP joint" and "locking screws or threaded holes." (EX1002, ¶¶343, 344). Claim 6 is directed to the "tarsometatarsal joint" and does not recite limitations related to locking screws or threaded holes. (EX1001, cl. 6). It appears that Mr. Sherman made a typographical error by copying portions of his Declaration at paragraphs 247 and 248 of IPR2022-000487. In view of Mr. Sherman's basis for combining Arnould, Zahiri, and Myerson at paragraphs 343 and 344, Mr. Sherman's analysis is

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OSTEOMED LLC
Petitioner,

v.

STRYKER EUROPEAN OPERATIONS HOLDINGS LLC ,
Patent Owner.

Case IPR2022-00488

U.S. Patent No. 10,993,751

DECLARATION OF DR. GEORGE B. HOLMES, JR., M.D., FAAOS
IN SUPPORT OF PATENT OWNER'S RESPONSE

STRYKER Exhibit 2007
Page 1 of 35
IPR2022-00488

(Ex. 1010) and the device disclosed in Zahiri (Ex. 1007), and how they would have been understood and used in a clinical setting by a foot & ankle surgeon in October 2008. I do not offer any opinions regarding the validity of the 751 patent.

IV. THE 751 PATENT

19. The 751 patent discloses "a plate for arthrodesis or osteosynthesis adapted to be fixed between two bone parts." (Ex. 1001 at 1:29-31). The 751 patent further recognizes that "this type of plate generally has holes for engaging screws, allowing arthrodesis between two bones or osteosynthesis between two bone fragments." (*Id.* at 1:33-35). These descriptions are consistent with the plain and ordinary meaning of a "bone plate" to a medical doctor as of October 2008.

20. In my opinion as an orthopedic surgeon, a "bone plate" generally refers to a plate that is positioned to span a joint or fracture where the plate includes holes through which bone screws can be engaged into the bone parts on each side of the joint or fracture. Bone plates are generally made of metal but can also be made of non-metal materials such as polyethetherketone (PEEK) and provide structural support to the bone(s) on either side of the joint or fracture.

V. SLATER

A. Ankle and Foot Bones

21. I understand that Mr. Sherman offers the opinion that "[a] POSITA

would understand that at least the talus and calcaneus are bones in the foot and that the ankle is an anatomical joint of the foot." (Ex. 1002 at ¶115). In my opinion, a POSITA would not consider the ankle joint, also known as the tibiotalar joint, to be an anatomical joint in the human foot**.**

22. The bones in the human foot include phalanges, metatarsal bones, and tarsal bones.

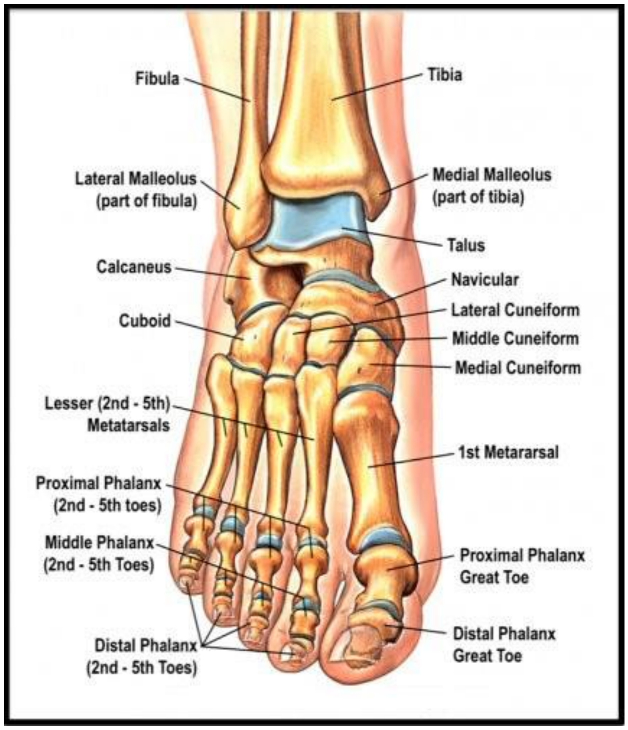
23. The phalanges (shown below) are the bones in the toes. The hallux (great toe) contains a proximal and a distal phalanx. The second to fifth toes each contain proximal, middle, and distal phalanges.

24. The metatarsal bones (shown below) connect to the phalanges distally and to the tarsal bones proximally. There are five metatarsals that are generally numbered as "first metatarsal," which connects with the hallux; "second metatarsal," which connects with the second toe; "third metatarsal," which connects with the third toe; "fourth metatarsal," which connects with the fourth toe;" and "fifth metatarsal," which sits at the outer edge of the foot and connects to the fifth toe (i.e., the "pinky toe").

25. The tarsal bones (shown below[1]) include the medial, intermediate, and

[1] Figure taken from www.FootEducation.com.

lateral cuneiforms, the cuboid, and the navicular. The tarsal bones also include the calcaneus ("heel bone") and the talus. The tarsal bones form the transverse and longitudinal arch of the foot.



26. The metatarsophalangeal joints ("MTP joints") refer to the joints between the metatarsals and the proximal phalanx of each toe. A "first MTP joint" refers to the joint between the first metatarsal and the proximal phalanx of the great toe. The first MTP joint is a common area for arthritis ("hallux rigidus") and foot pain. Ambulation activities such as running and walking can cause cartilage in the first MTP joint to wear away over time.

27. The tarsometatarsal joints ("TMT joints") refer to the joints between the tarsals and the metatarsals.

28. The tibia (shown above) and fibula (shown above) are bones in the leg. The ankle is comprised of articulations between the distal tibia, the distal fibula, and the talus. The ankle joint is generally understood to be the tibiotalar joint, which is the joint between the tibia and the talus. The ankle joint connects the leg with the foot. The ankle joint allows up (dorsiflexion) and down (plantarflexion) movement of the foot.

29. The subtalar joint is the joint between the talus and the calcaneus. The subtalar joint allows for inversion and eversion of the foot.

30. Bone plates used in the foot are typically placed on the dorsal side of the foot because on the one hand it would be technically difficult to place a plate on the plantar surface while on the other hand such a plantar placement would lead to wound problems and painful walking (gait). The dorsum of the foot only has a thin layer of skin and subcutaneous tissue covering it. To accommodate the thin layer of skin, bone plates used in the foot must have a low profile. Any abrupt protrusions would predispose the patient's skin, dorsal soft tissues, and tendons to tear or rupture and would also predispose the patient to develop wound complications and infection.

B. Elongated Openings 99 and 100 in Slater's Ankle Fusion Plate

31. Slater discloses a bone plate specifically designed for ankle fusion. In

VI. ARNOULD

43. Arnould discloses a bone plate for fusion of an MTP joint. Specifically, Arnould "relates to an arthrodesis plate for a metatarsal-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe." (Ex. 1006 at ¶1). The Arnould plate features a leg that allows the plate to be attached to a dorsal-lateral surface of the epiphysis of the phalanx, where the bone is generally solid. (*Id.* at ¶3). The end of the leg includes a hole that receives a long screw that extends through the epiphyseal zone of the phalanx into the metatarsal epiphysis. (*Id.*).

44. Arnould discloses specific "surgical steps" that include, amongst others, "[p]artially immobilizing the plate body on the metatarsal, allowing relative freedom of movement generally along the longitudinal direction of the plate body" and "[p]ermanently immobilizing the plate body on the metatarsal and phalanx." (Ex. 1006 at ¶8). This partial immobilization, i.e., temporary fixation, is achieved with the use of oblong hole 16 and screw 2 shown below.

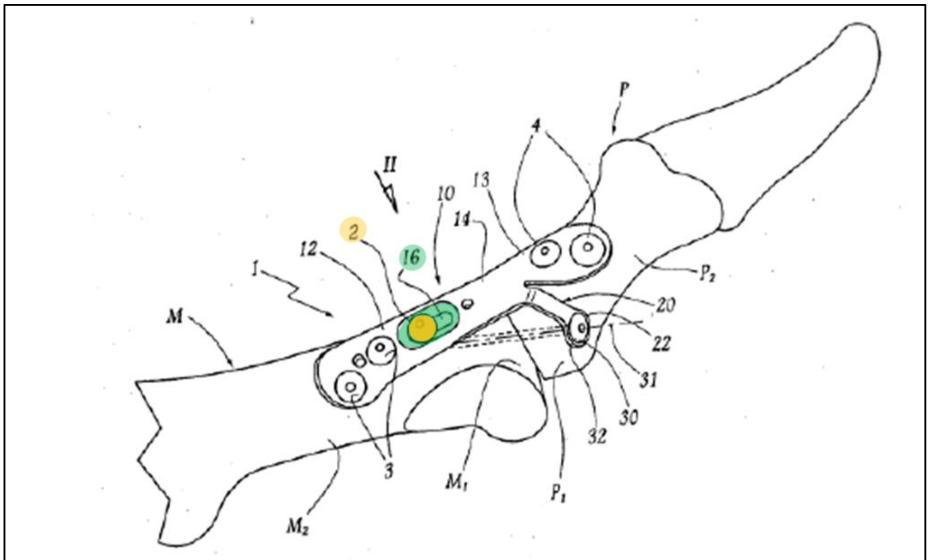


Fig. 1

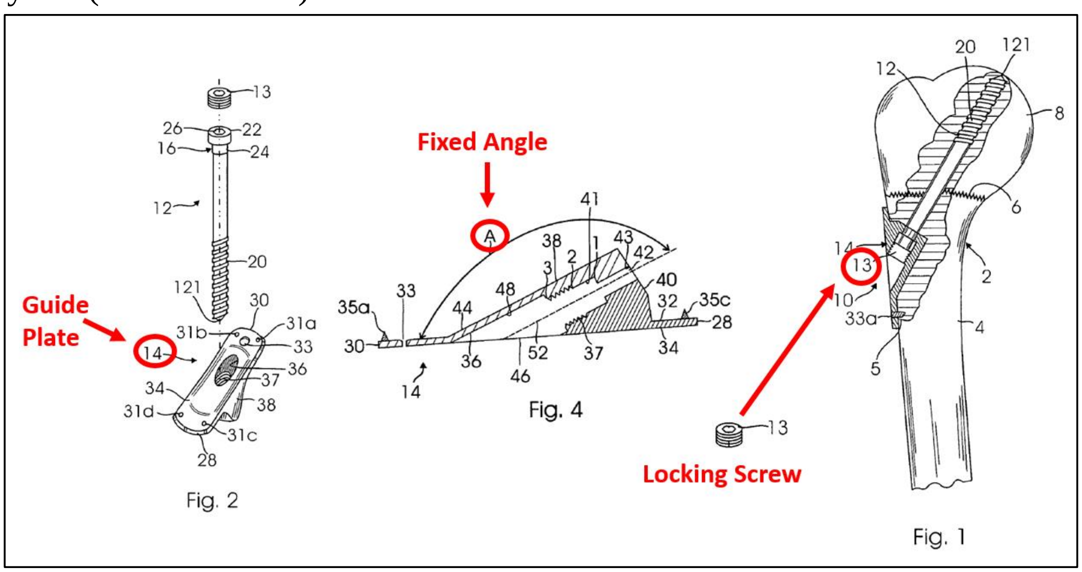
(Ex. 1006 at Fig. 1).

45. In particular, Arnould discloses that after the plate is placed across the metatarsophalangeal joint, "the plate body 10 is then partially immobilized using the oblong hole 16: the surgeon inserts a screw 2 (Fig. 1) into the hole 16, on the side of the rear bottom 16_2 of this hole, without tightening the screw head against the edge of the hole. In this way, the plate body 10 remains displaceable in the direction 11 relative to the metatarsal M." (*Id.* at ¶31). This displacement permits alignment adjustments of the plate. While screw 2 temporarily holds the plate over the joint, screw 30 is inserted to obtain compression between the proximal phalanx and the metatarsal. (*Id.* at ¶32). At this point, "screw 2 is then completely screwed and tightened into the hole 16 in order to completely secure the plate body 10 to the

metatarsal M." (*Id.* at ¶33). A POSITA would understand that using screw 2 in this manner serves to partially immobilize the Arnould plate across the metatarsophalangeal joint while the long screw is inserted through the hole in the leg 20 and screwed in, "bring[ing] the metatarsal M closer to the phalanx P, with this movement being guided along the direction 11 by the cooperation of the oblong hole 16 and the loose screw 2." (*Id.* at ¶32).

VII. ZAHIRI

46. Zahiri describes a fixation device for both a transverse and longitudinal fracture located at the junction of the metaphysis and diaphysis of a long bone such as the proximal humerus. (Ex. 1007 at 2:16-20). The Zahiri device includes a barrel to guide a lag screw at a fixed angle across a proximal humeral fracture and to mate with a locking screw on the top of the lag screw once the lag screw is settled into the epiphysis. (*Id.* at Abstract).



47. In my opinion, Zahiri does not disclose a bone plate. Rather, Zahiri discloses a structural configuration for positioning a lag screw across a proximal humeral fracture. Zahiri does not incorporate a bone plate into its structural configuration.

48. Instead, Zahiri incorporates what it refers to as a “guide plate” into its structural configuration. The Zahiri “guide plate” functions as a washer by taking stress from the screw head and distributing the stress over the larger area of the “guide plate.” The Zahiri “guide plate” also prevents the screw from impinging or migrating into the bone, and provides a structure in which a locking screw can be threaded to prevent loosening of the screw. However, a medical doctor would understand that the Zahiri “guide plate” does not and cannot provide any structural support to immobilize the bone fragments drawn into compression by the lag screw because, for example, it does not have the length or structural integrity of a bone plate.

49. Rather, the purpose of the structural configuration of the Zahiri device is to guide the insertion of the lag screw. (*Id.* at 3:26-31 (“It has additionally been discovered, according to the present invention, that with the aid of a newly designed hollow cylinder placed inside of the barrel of the guide plate, the guide plate can be further used to help make a guide hole on the bone for guiding the lag screw precisely

to settle into the bone at a desired angle.”)). In fact, Zahiri discloses “a procedure to make a guide hole for the lag screw 12.” (*Id.* at 6:49-50). Specifically, Zahiri explains that, in order to make the guide hole in the proximal humerus, the guide plate 14 and short barrel portion 38 are temporarily inverted so that “the backside 34 of the plate 14 contacts the bone cortex” and a drilling guide 15 can be “slidably inserted into the passage 52 of the short barrel 38.” (*Id.* at 6:50-64). Zahiri goes on to explain that “a long drill shaft from a conventional drill is inserted into the hole of the drilling guide 15” to make the guide hole at the “same angle as that of the barrel 38.” (*Id.* at 6:63-67). After the guide hole is created, the “guide plate 14 is removed” and “the newly created hole can host the barrel 38 portion of the guide plate 14” for insertion of the lag screw. (*Id.* at 7:4-9). In sum, the Zahiri device is “used to help make a guide hole on the bone for guiding the lag screw precisely to settle into the bone at a desired angle.” (*Id.* at 2:51-54). The ability to achieve a desired angle with such precision is a function of the engagement between the geometry of the barrel portion and the surfaces of the lag screw and the locking screw. (*Id.* at 6:12-35).

50. I understand that Mr. Sherman has opined that “[a] POSITA would understand that there are no practical differences between fusing a joint through arthrodesis and fusing a bone fracture. A POSITA would know that bone plates

configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to the prior art inclusive of Zahiri when making improvements to Slater's bone plate." (Ex. 1002 at ¶134).

51. While I agree that some bone plates may be used for arthrodesis and for osteosynthesis, this is not true of every bone plate. Whether or not a bone plate can be used for arthrodesis and osteosynthesis depends on the particular characteristics of the bones being fixed. Such characteristics include, for example, the size of the bones and/or fracture to be fixed, their geometry, the quality of the bone, the amount and quality of soft tissue present, and the normal loads being placed on the bone(s).

52. As discussed above, Zahiri is not a bone plate. Zahiri discloses a structural configuration that includes a "guide plate" that is specifically designed for use with a corresponding lag screw for fixing fractures of the proximal humerus (typically a broken shoulder). A proximal humeral fracture refers to a break involving the area surrounding the humeral head, which is commonly known as the ball of the shoulder's ball and socket joint. Proximal humeral fractures are often the result of a patient with poor bone density (commonly elderly patients) falling onto an outstretched arm.

53. A POSITA would have understood that Slater's bone plate and Zahiri's

structural configuration cannot be used interchangeably because there are many practical differences between fusing an ankle joint and guiding a lag screw across a proximal humeral fracture. For example, the ankle joint is a hinge, weight-bearing joint with range of motion primarily confined to one plane (dorsiflexion and plantarflexion). The shoulder comprised of the proximal humerus is a ball and socket (rounded), non-weight-bearing joint that allows range of motion in multiple planes. In fact, the Zahiri device cannot be used for shoulder fusion. *See, e.g.,* Ex. 1002 at ¶39.

54. I understand that Mr. Sherman has opined that "[a] POSITA would understand that there are no practical differences between stabilizing a joint for the purpose of arthrodesis and stabilizing two bone parts for the purpose of fusing a bone fracture. A POSITA would know that bone plates configured for arthrodesis and bone plates configured to fuse bone fractures have been used interchangeably for decades. Therefore, a POSITA would look to Zahiri when making improvements to Arnould's bone plate." (Ex. 1002 at ¶249).

55. While I agree that some bone plates may be used for arthrodesis and for osteosynthesis, this is not true of every bone plate for the reasons stated above. In particular, in my opinion, a POSITA would have understood that Arnould's bone plate and Zahiri's structural configuration cannot be used interchangeably because

there are many practical differences between fusing an MTP joint and guiding a lag screw across a proximal humeral fracture.

56. For example, the MTP joint is relatively flat but conical only allowing motion in one plane (the sagittal plane) whereas the proximal humerus is more rounded allowing motion in multiple planes. Therefore the fixation requirements are different due to the stark anatomical and biomechanical differences between fusing the MTP joint and fixing a proximal humeral fracture. As such, a POSITA would understand that Arnould's bone plate and Zahiri's structural configuration are not interchangeable.

VIII. Combining Slater and Zahiri

57. I understand that Mr. Sherman opines that "a POSITA would look to . . . Zahiri when making improvements to Slater's bone plate." (Ex. 1002 at ¶134.) Mr. Sherman further opines that "a POSITA would be motivated to combine the teachings of Slater and Zahiri," (Ex. 1002 at ¶139), namely that "the temporary pin holes, as disclosed in Zahiri, could be implemented into Slater's bone plate to guide the plate alignment during implantation." (Ex. 1002 at ¶138.) I disagree that a POSITA would have been motivated to implement Zahiri's temporary guide pins and temporary pin holes into the Slater ankle fusion plate.

58. The Zahiri device is a small device designed to be positioned at the diaphyseal cortex of the proximal humerus. I understand that Zahiri's motivation

for including the specially designed pins for insertion into four pin holes, as well as the four tips, into the Zahiri structural configuration was to help stabilize the Zahiri plate during insertion of the lag screw. (Ex. 1007 at 1:50-61, 2:37-43).

59. In my opinion, a POSITA would not have been motivated to incorporate Zahiri's temporary pin holes into Slater's bone plate because—unlike Zahiri—Slater's bone plate (1) is designed to span the ankle joint, which is relatively flat; and (2) already includes multiple, pre-existing openings that can be used to stabilize the plate during insertion of the angled screw.

60. A POSITA would understand that partially inserting a screw into one of the elongated holes (openings 99 or 100) of the Slater plate serves to stabilize the plate prior to and during insertion of the angled screw. After the angled screw is inserted, the partially inserted screw can be fully inserted for permanent fixation. This process negates the need for any smaller temporary fixation pins or pin holes such as the ones used in the Zahiri device.

61. For a structural configuration like Zahiri that is used in the proximal humerus and is therefore more susceptible to unwanted torqueing or spinning, a surgeon understands that there is more of a need for temporary fixation members and tips than with bone plates used on the ankle or foot. In contrast, Slater's bone plate is not at risk for unwanted torqueing or spinning because of its size and shape

as well as the size and shape of the ankle joint. Without the temporary fixation pins and tips, the Zahiri device "is unstable in operation when the lag screw is pushed and turned to settle into the bone." (Ex. 1007 at 1:51-57, 2:37-43). And unlike the ankle plate in Slater, which has multiple fixation screws on both sides of a bone discontinuity, for the guide plate in Zahiri, all fixation screws are on only one side of a bone discontinuity.

62. For at least these reasons, a POSITA would not have been motivated to combine the "temporary pin holes" of Zahiri with the plate of Slater.

IX. Combining Arnould with Zahiri

63. I understand that Mr. Sherman opines that "a POSITA would be motivated to combine the teachings of Arnould and Zahiri to utilize a known technique for improving the implantation of a bone plate (similar device) and obtain a similar improvement."." (Ex. 1002 at ¶256). I disagree.

64. A POSITA would not be motivated to combine Zahiri's temporary guide pins and pin holes because the Arnould plate does not require the temporary fixation features of Zahiri. As explained above, Arnould expressly teaches that pre-existing screw 2 and oblong hole 16 of Arnould would have been used to "partially immobilize" the bone plate across the metatarsophalangeal joint while the long screw is inserted through the hole in the leg and across the MTP joint. The screw 2 is later "completely screwed and tightened into the hole 16 in order to completely

secure the plate body 10 to the metatarsal M." (Ex. 1006 at ¶¶8, 31-33).

65. Unlike Zahiri's structural configuration, the Arnould bone plate is not at risk for unwanted torqueing or spinning because of its size and shape as well as the size and shape of the MTP joint. Specifically, Arnould's bone plate is designed and contoured to span the MTP joint with fixation of the plate to the metatarsal and to the phalanx, with a leg portion configured to wrap around the phalangeal epiphysis. (Ex. 1006 at ¶23). Additionally, Arnould's bone plate avoids unwanted torqueing and spinning because, before inserting the cross screw 30 into hole 25, Arnould is "partially immobilized" by inserting screw 2 into oblong hole 16 without tightening the screw head against the edge of the hole, allowing displacement only in the direction 11 relative to the metatarsal M. (*Id.* at ¶31). In short, partial immobilization is achieved without the need for temporary fixation pins or pin holes.

66. As such, a POSITA would understand that the Arnould plate does not require the temporary fixation pins and pin holes of Zahiri. For at least these reasons, a POSITA would not have been motivated to combine Zahiri with the plate of Arnould.

X. CONCLUSION

67. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful

CONCISE OXFORD ENGLISH DICTIONARY

Concise Oxford English Dictionary

ELEVENTH EDITION, REVISED

Edited by
Catherine Soanes
Angus Stevenson

OXFORD
UNIVERSITY PRESS

kangaroo. [Genera *Bettongia* and *Aepyprymnus*.]
– ORIGIN C19: from Dharuk.

between ■ prep. & adv. **1** at, into, or across the space separating (two objects, places, or points). **2** in the period separating (two points in time). **3** [as prep.] indicating a connection or relationship involving two or more parties. **4** [as prep.] by combining the resources or actions of (two or more parties).
– PHRASES **between ourselves** (or **you and me**) in confidence. **(in) between times** (or **whiles**) in the intervals between other actions.
– ORIGIN OE *betwēonum*, from *be* 'by' + a Gmc word rel. to TWO.

USAGE

Say **between you and me**, rather than **between you and I**. A preposition such as **between** takes the object case and is correctly followed by object pronouns such as **me, him, her,** and **us** rather than subject pronouns such as **I, he, she,** and **we**. Thus it is right to say **between us** or **between him and her** and it is clearly wrong to say **between we** or **between he and she**.

betwixt ■ prep. & adv. archaic term for BETWEEN.
– PHRASES **betwixt and between** informal neither one thing nor the other.
– ORIGIN OE *betwēox*, from *be* 'by' + a Gmc word rel. to TWO.

beurre blanc /bəː ˈblɒ̃/ ■ n. a creamy sauce made with butter, onions, and vinegar or lemon juice.
– ORIGIN Fr., lit. 'white butter'.

BeV ■ abbrev. another term for GEV.
– ORIGIN 1940s: from *b*illion (10^9) *e*lectron*v*olts.

bevatron /ˈbɛvətrɒn/ ■ n. a synchrotron used to accelerate protons to energies in the billion electronvolt range.
– ORIGIN 1940s: from BEV + -TRON.

bevel /ˈbɛv(ə)l/ ■ n. **1** (in carpentry) a surface or edge which slopes away from a horizontal or vertical surface. **2** (also **bevel square**) a tool for marking angles in carpentry and stonework. ■ v. (**bevels, bevelling, bevelled**; US **bevels, beveling, beveled**) [usu. as adj. **bevelled**] cut a bevel on.
– ORIGIN C16: from an OFr. dimin. of *baif* 'open-mouthed', from *baer* (see BAY³).

bevel gear ■ n. a gear working another gear at an angle to it by means of bevel wheels.

bevel wheel ■ n. a toothed wheel whose working face is oblique to the axis.

beverage /ˈbɛv(ə)rɪdʒ/ ■ n. a drink other than water.
– ORIGIN ME: from OFr. *bevrage*, based on L. *bibere* 'to drink'.

bevvy /ˈbɛvi/ ■ n. (pl. **bevvies**) Brit. informal an alcoholic drink.
– DERIVATIVES **bevvied** adj.
– ORIGIN C19: abbrev. of BEVERAGE.

bevy /ˈbɛvi/ ■ n. (pl. **bevies**) a large group of people or things.
– ORIGIN ME: of unknown origin.

bewail ■ v. greatly regret or lament.
– DERIVATIVES **bewailer** n.

beware ■ v. be cautious and alert to risks or dangers.
– ORIGIN ME: from the phr. *be ware* (see BE-, WARE³).

bewhiskered ■ adj. having hair or whiskers growing on the face.

Bewick's swan ■ n. a bird of the Eurasian race of the tundra swan. [*Cygnus columbianus bewickii*.]
– ORIGIN from the name of the English artist and engraver Thomas *Bewick* (1753–1828).

bewigged ■ adj. (of a person) wearing a wig.

bewilder ■ v. [often as adj. **bewildered**] perplex or confuse.
– DERIVATIVES **bewilderedly** adv. **bewildering** adj. **bewilderingly** adv. **bewilderment** n.
– ORIGIN C17: from BE- + obs. *wilder* 'lead or go astray', of unknown origin.

bewitch ■ v. **1** cast a spell over. **2** enchant and delight.
– DERIVATIVES **bewitcher** n. **bewitching** adj. **bewitchingly** adv. **bewitchment** n.
– ORIGIN ME: from BE- + WITCH.

bey /beɪ/ ■ n. (pl. **beys**) historical the governor of a district or province in the Ottoman Empire.
– ORIGIN Turk., mod. form of *beg* 'prince, governor'.

beyond ■ prep. & adv. **1** at or to the further side of. ➤ more extensive or extreme than. **2** happening or continuing after. **3** having reached or progressed further than (a specified level or amount). **4** to or in a degree where a specified action is impossible. ➤ too advanced for. **5** [with neg.] apart from; except. ■ n. (**the beyond**) the unknown, especially in references to life after death.
– ORIGIN OE *begeondan*, from *be* 'by' + *geondan*, of Gmc origin.

bezant /ˈbɛz(ə)nt/ ■ n. **1** historical a gold or silver coin originally minted at Byzantium. **2** Heraldry a roundel or (i.e. a solid gold circle).
– ORIGIN ME: from OFr. *besant*, from L. *Byzantius* 'Byzantine'.

bezel /ˈbɛz(ə)l/ ■ n. a grooved ring holding the cover of a watch face or other instrument in position. ➤ a groove holding the crystal of a watch or the stone of a gem in its setting.
– ORIGIN C16: from OFr., of unknown origin.

bezique /bɪˈziːk/ ■ n. a trick-taking card game for two, played with a double pack of sixty-four cards, including the seven to ace only in each suit. ➤ the holding of the queen of spades and the jack of diamonds in bezique.
– ORIGIN C19: from Fr. *bésigue*, perh. from Pers. *bāzīgar* 'juggler' or *bāzī* 'game'.

bezoar /ˈbiːzɔː, ˈbɛzəʊɑː/ ■ n. **1** a small stony concretion which may form in the stomachs of certain animals, formerly used as an antidote for various ailments. **2** a wild goat with flat scimitar-shaped horns, the ancestor of the domestic goat. [*Capra aegagrus*.]
– ORIGIN C15: from Fr. *bezoard*, based on Arab. *bāzahr*, from Pers. *pādzahr* 'antidote'.

b.f. ■ abbrev. (in bookkeeping) brought forward.

BFPO ■ abbrev. British Forces (or Field) Post Office.

BG ■ abbrev. Bulgaria (international vehicle registration).

BGH ■ abbrev. bovine growth hormone.

BH ■ abbrev. Belize (international vehicle registration).
– ORIGIN from *British Honduras* (former name for Belize).

Bh ■ symb. the chemical element bohrium.

Bhagwan /bʌgˈwɑːn/ ■ n. Indian God.
– ORIGIN from Hindi *bhagwān*.

bhajan /ˈbʌdʒ(ə)n/ ■ n. Hinduism a devotional song.
– ORIGIN from Sanskrit *bhajana*.

bhaji /ˈbɑːdʒi/ (also **bhajia**) ■ n. (pl. **bhajis, bhajia**) (in Indian cuisine) a small flat cake or ball of vegetables, fried in batter.
– ORIGIN from Hindi *bhājī* 'fried vegetables'.

bhakti /ˈbʌkti/ ■ n. Hinduism devotional worship directed to one supreme deity, usually Vishnu or Shiva.
– ORIGIN from Sanskrit.

bhang /baŋ/ (also **bang**) ■ n. the leaves and flower-tops of cannabis, used as a narcotic in India.
– ORIGIN from Hindi *bhāṅg*.

bhangra /ˈbɑːŋgrə/ ■ n. a type of popular music combining Punjabi folk traditions with Western pop music.
– ORIGIN 1960s (denoting a traditional folk dance): from Punjabi *bhāṅgrā*.

bharal /ˈbʌr(ə)l/ ■ n. a Himalayan wild sheep with a bluish coat and backward-curving horns. [*Pseudois nayaur*.]
– ORIGIN C19: from Hindi.

bhelpuri /ˈbeɪlˌpuːri/ ■ n. an Indian dish of puffed rice, onions, spices, and hot chutney.
– ORIGIN from Hindi *bhel* 'mixture' + *pūrī* 'deep-fried bread'.

bhikkhu /ˈbɪkuː/ (also **bhikku**) ■ n. a Buddhist monk or devotee.
– ORIGIN Pali, from Sanskrit *bhikṣú* 'beg'.

bhindi /ˈbɪndiː/ ■ n. Indian term for OKRA.
– ORIGIN from Hindi *bhiṇḍī*.

b.h.p. ■ abbrev. brake horsepower.

bhuna /ˈbuːnə/ (also **bhoona**) ■ n. a medium-hot dry curry originating in Bengal.

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Paper 46
Date: March 8, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01450
Patent 8,529,608 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges.*

Opinion by the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* SNEDDEN.

DECISION
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") and OsteoMed LLC ("Patent Owner"). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–6, 8–14, and 17 ("Challenged Claims") of U.S. Patent No. 8,529,608 B2 ("the '608 patent," Ex. 1001) are unpatentable.

A. Background and Summary

Petitioner filed a Petition requesting an *inter partes* review of claims 1–6, 8–14, and 17 of the '608 patent. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 5.

Following institution, Patent Owner filed a Response to the Petition (Paper 21, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 29, "Reply"), and Patent Owner filed a Sur-Reply (Paper 33, "Sur-Reply").

On December 15, 2022, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 42.

B. Related Matters

Petitioner has filed petitions for *inter partes* review in IPR2021–01451, IPR2021–01452, and IPR2021–01453 for related U.S. Patent Nos. 9,351,776; 9,763,716; and 10,245,085, respectively. Pet. 1–2; Paper 4, 1–2. The parties indicate that the '608 patent is asserted against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.)

and in *OsteoMed LLC v. Wright Medical Technology, Inc.*, Case No. 1:20-cv-1621 (D. Del.). *Id.*

The parties also indicate as related matters, IPR2022–00189, involving the ’608 patent, and IPR2022–00190 and IPR2022–00191 for U.S. Patent Nos. 9,351,776 and 9,763,716, respectively. Paper 15, 2; Paper 26, 2.

C. The ’608 patent (Ex. 1001)

The ’608 patent discloses a “system for securing bones together across a joint.” Ex. 1001, Abstract. The system may be used for reconstructing a joint that has been damaged due to bone or soft tissue trauma, in which a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint. *Id.* at 1:12–16.

The ’608 patent discloses that its system has “the ability to tightly couple the bones of a joint together” by including a transfixation screw that is inserted across the joint through a bone plate. *Id.* at 2:22–26. More specifically, the ’608 patent discloses that the presence of the transfixation screw across the joint “may increase the contact pressure on the bony interface of the joint, increasing the probability of a positive fusion.” *Id.* at 2:38–41. According to the ’608 patent, by having the transfixation screw passing from the first bone to the second bone, a “tension band” construct is created “that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint,” thereby enhancing the integrity and reliability of the plate and increasing the load that the plate may support without increasing plate thickness. *Id.* at 2:45–52.

Figure 2, reproduced below, shows “a bone plate being used in conjunction with a transfixation screw to repair the failed metatarso-

phalangeal joint" and immediately below it is Figure 3, which shows "a more detailed isometric view of the bone plate." *Id.* at 3:1–6.

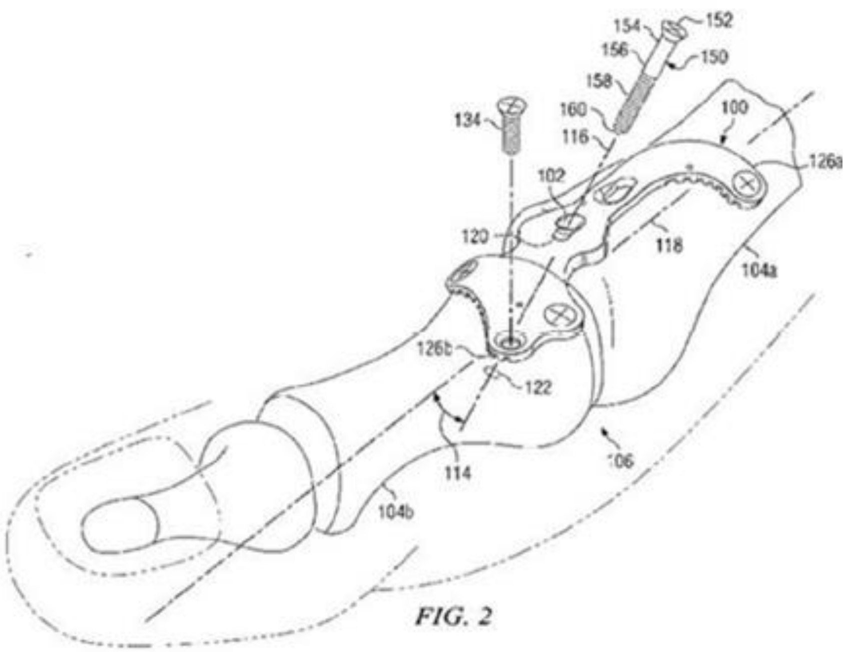

FIG. 2

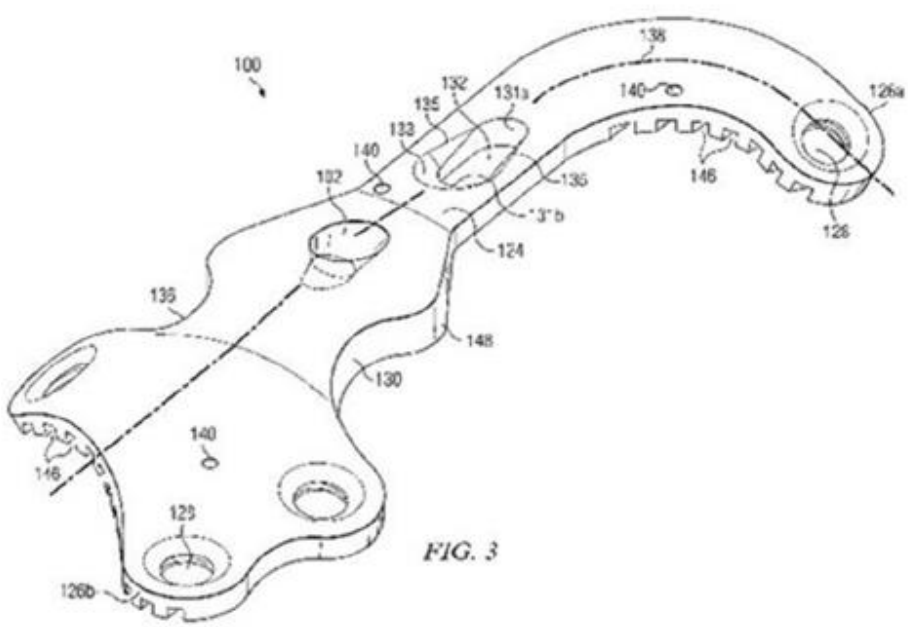

FIG. 3

Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id*. at 4:3–8. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b "in order to fuse joint 106." *Id*. at 4:19–25. Figure 3 shows bone plate 100 having elongated spine 124 and bridge portion 130 between first end 126a and second end 126b that can span across joint 106. *Id*. at 7:18–26. First end 126a includes attachment point 128 "for attaching first end 126a to bone 104a" and second end 126b includes another attachment point 128 "for attaching second end 126b to bone 104b." *Id*. The '608 patent discloses that bridge portion 130 "is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130" and may include thickened section 136 of bone plate 100 "to increase the bending strength of bridge portion 130." *Id*. at 8:2–9.

D. Illustrative Claims

Independent claims 1 and 11, reproduced below, are illustrative of the claimed subject matter of the '608 patent.

> 1. A system for securing two discrete bones together across a joint between the two bones, comprising:
>
> the plate comprises:
>
> an elongate spine having:
>
> a first end comprising: at least one fixation point for attaching the first end to a first discrete bone on a first side of an intermediate joint; and a first inner surface configured to substantially conform with a geometry of the first discrete bone;
>
> a second end comprising: at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint;

and a second inner surface configured to substantially conform with a geometry of the second discrete bone; and

a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint, at least a portion of said bridge portion having a thickness greater than at least a portion of the thickness of either the first end or the second end; and

a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends [through][1] the bridge portion at a trajectory configured to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone once the plate is placed across the joint; and

the transfixation screw comprises a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion.

11. A plate for securing two discrete bones together across an intermediate joint, comprising:

an elongate spine having:

a first end comprising: at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and a first inner surface configured to substantially conform with a geometry of the first bone;

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[1] The term "through" was added by Certificate of Correction. Ex. 1005, page 14.

> a second end comprising: at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and a second inner surface configured to substantially conform with a geometry of the second bone; and
>
> a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint; and
>
> a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge, wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends.

Ex. 1001, 11:57–12:31, 13:4–14:2.

Claims 2–6 and 8–10 depend from independent claim 1. *Id.* at 12:32–50, 12:56–13:3. Claims 12–14 and 17 depend from independent claim 11. *Id.* at 14:3–14, 26–30.

E. Evidence

Petitioner relies upon information that includes the following.

Ex. 1005, Slater, WO 2007/131287 A1, published Nov. 22, 2007 (“Slater”).

Ex. 1006, Falkner, Jr., U.S. 2005/0171544 A1, published Aug. 4, 2005 (“Falkner”).

Ex. 1007, Arnould, EP 1897509 B1, published Mar. 12, 2008.

Ex. 1008, Translation of EP 1897509 B1 (“Arnould”).

Ex. 1009, Weaver et al., US 6,623,486 B1, issued Sept. 23, 2003 ("Weaver").

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1027) and Dr. George B. Holmes, Jr. (Ex. 1028) to support its contentions.

Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

F. Asserted Ground of Unpatentability

Petitioner asserts that claims 1–6, 8–14, and 17 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–5, 9–14, 17	102	Slater
2	6, 8	103	Slater, Weaver
3	1–3, 6, 8–13, 17	102	Falkner
4	4, 5, 14	103	Falkner, Arnould
5	1–5, 9–14, 17	103	Arnould, Slater
6	6, 8	103	Arnould, Slater, Weaver

II. ANALYSIS

A. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner takes the position that "[t]here are no claim terms in the Challenged Claims that require construction" and that Petitioner has "applied the ordinary and customary meaning of each claim term." Pet. 8–9 (*citing Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)).

Patent Owner contends that the term "trajectory" as used in the Challenged Claims "means a fixed angle relative to the neutral bending axis of the joint." PO Resp. 18. Patent Owner's proposed construction is relevant to Ground 1 and our discussion below regarding whether Slater is anticipatory.

Having considered the parties' positions and evidence of record, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent further discussion of the meaning any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

B. Summary of Cited Prior Art

1. Summary of Slater (Ex. 1005)

Slater relates to an ankle fusion plate for fusion of the anterior ankle. Ex. 1005, 1:6–7. Slater discloses that orthopedic devices can repair diseased bones and bone fractures. *Id.* at 1:21–22. Slater explains that bones that have been fractured must be kept together for lengthy periods of time to permit recalcification and bonding. *Id.* at 3:1–3. According to Slater,

internal fixation techniques require "the fracture be stable axially, torsionally and rotationally." *Id.* at 3:19–25; 7:1–2. To achieve such objectives, Slater discloses a fixation screw and plate design in which "the plate depth changes at different locations" so that "the depth at the beginning a[n]d end points of the L shaped contour [of the plate] over the ankle joint in the second region will be at it[s] maximum thickness." *Id.* at 8:27–34. Slater further discloses that "[t]he plate will taper at least one but preferably two different points of the plate" and that "[t]hese points will preferably resemble and conform to the typical geometry of the anatomical region." *Id.* at 9:3–4, 11–12.

Figure 1, reproduced below, shows a side elevation view of a plate attached via fixation screws "to an abbreviated ankle joint (dotted lines)." *Id.* at 9:28–30.

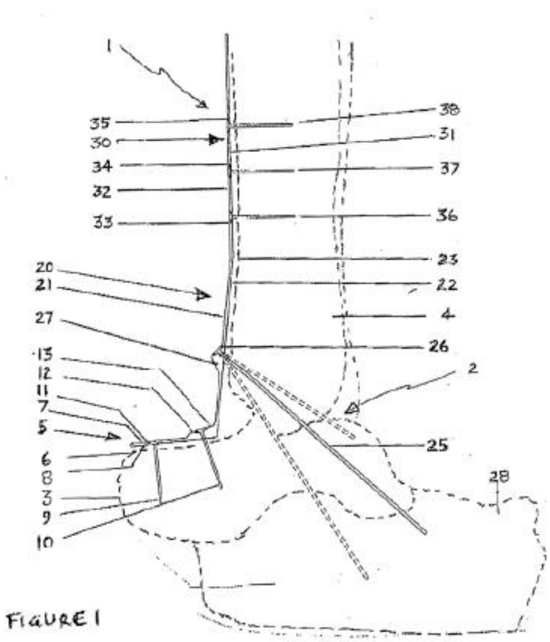


FIGURE 1

Figure 1 shows fusion plate 1 attached to the talus bone 3 and the tibial bone 4 that form ankle joint 2. *Id.* at 11:1–4. Fusion plate 1 includes portion 5 "disposed in a first plane which generally aligns with" anterior surface 6 of the talus bone 3 for fixation thereto. *Id.* at 11:5–8. Disposed in portion 5 are

fixation screws 9 and 10 which pass through openings 11 and 12 of portion 5 to engage the talus bone 3. *Id.* at 11:8–9. Portion 20 of fusion plate 1 has formation 27 with opening 26 disposed therein for allowing fixation screw 25 to pass therethrough. *Id.* at 11:18–21. "Formation 27 is configured so that [fixation] screw 25 is implanted at an angle within a predetermined allowable angular range" such that fixation screw 25 engages the tibia bone 4, the talus bone 3, and the calcaneus bone 28. *Id.* at 11:21–24. Portion 30 of fusion plate 1 includes openings 33, 34, and 35 which receive fastening screws 36, 37, and 38 to engage tibia bone 4. *Id.* at 11:27–31.

2. Summary of Falkner (Ex. 1006)

Falkner relates to systems for fixing bones using bone plates having apertures for retaining fasteners. Ex. 1006, Abstract. Falkner discloses that fixation of bone fractures can be problematic when these fractures are disposed near the ends of bones. *Id.* ¶ 4. Falkner purports to resolve past problems of achieving an interference fit that is tight enough to prevent slippage of a blade portion of the bone plate relative to an interlocking bone screw. *Id.* ¶ 6.

Figure 1, reproduced below, shows a sectional view of a system for fixing bones using a bone plate with a toothed aperture such that the bone plate is secured to a fractured bone. *Id.* ¶ 8.

Fig. 1

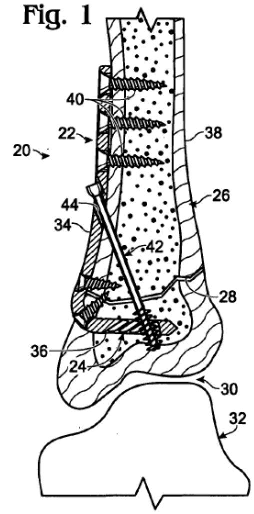


Figure 1 shows system 10 including bone plate 22 with toothed aperture 24 in which bone plate 22 "may be positioned on and/or in any suitable bone(s) to span . . . within a bone or between bones" such as on a region of the tibia bone 26 that spans fracture 28, as depicted. *Id.* ¶ 21. Thus, bone plate 22 may span joint 30 between tibia bone 26 and talus bone 32. *Id.* Bone plate 22 includes first plate portion 34 and second plate portion 36. *Id.* ¶ 22. Falkner discloses that bone screws 40 "may be placed into bone from any suitable number of openings of the bone plate." *Id.* ¶ 23. Threaded fastener 42 may extend through opening 44 and toothed aperture 42 of bone plate 22. *Id.* ¶ 24. Falkner discloses that bone plate 22 "may be sized and shaped to conform to particular portions of a bone (or bones)" and "may be thicker and thus stronger in regions where they may not need to be contoured, such as along the shaft of the bone." *Id.* ¶¶ 33, 35. Thickness of bone plate 22 "may be varied within" and a thicker portion may be provided to "increase structural stability." *Id.* ¶ 35.

3. Summary of Arnould (Ex. 1008)

Arnould "relates to an arthrodesis plate for a metatarsal-phalangeal joint." Ex. 1008 ¶ 1. Arnould discloses that a leg of its plate "allows the

plate to be attached to a lateral surface of the epiphysis of the phalanx." *Id.* ¶ 6. Arnould explains that "this leg is shaped so that its end hole can receive a long screw . . . which will extend both through the bone material of the phalanx and into the bone material of the metatarsal." *Id.* Thus, the "long screw extends lengthwise in a direction having an anteroposterior component, so that this screw essentially, if not exclusively, takes up the bending stresses generated during the patient's walking." *Id.*

Figure 1, reproduced below, shows a perspective view of an arthrodesis plate placed and fixed on a metatarsal-phalangeal joint locked by the plate. *Id.* ¶ 10.

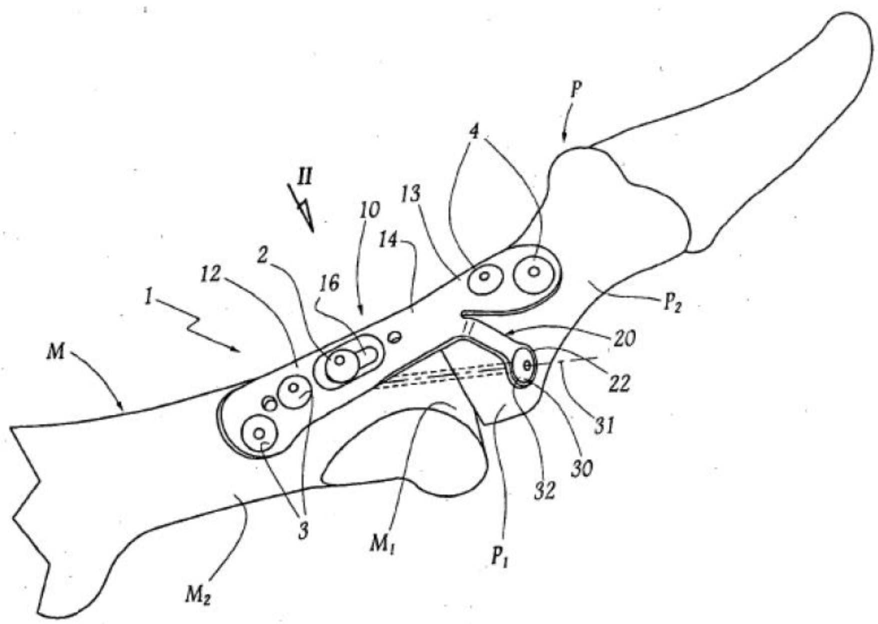


Fig. 1

Figure 1 shows arthrodesis plate 1 on a joint between metatarsal M and first phalanx P of a toe. *Id.* ¶ 11. Plate 1 includes plate body 10 and leg 20. *Id.* ¶ 13. Screws 3 and 4 secure opposite ends of plate body 10 via holes in the plate body to the bones as shown. *Id.* ¶¶ 33–34.

Leg 20 is provided with a through-hole for receiving screw 30 that has sufficient length to extend from the through-hole "into both the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, and possibly also into the metatarsal diaphysis M_2." *Id.* ¶ 26. Arnould discloses that "the leg 20 is bent downward relative to the plate body 10 along a bend line 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the leg and the phalangeal portion 13." *Id.* ¶ 24. Between the metatarsal portion 12 and phalangeal portion 13, there is a "zone 14" described as a "joint zone" or "junction zone." *Id.* ¶ 71. Arnould discloses that it is advantageous to include a junction zone with a "bending line 141" to allow "better adaptation of the plate body 10 to the anatomy of the joint when it is locked." *Id.* ¶ 20.

4. Summary of Weaver (Ex. 1009)

Weaver is directed to a bone plating system for fracture fixation, which includes a bone plate having plate holes for both locking and non-locking screws. Ex. 1009, 1:10–13. Weaver discloses that "[s]ecuring the screws to the plate provides a fixed angle relationship between the plate and screw and reduces the incidence of loosening" and such screws are called "locking screws." *Id.* at 1:46–49. According to Weaver, a known locking screw has threading on an outer surface of its head that mates with corresponding threading on the surface of a plate hole to lock the screw to the plate. *Id.* at 1:49–54. Weaver discloses that "locking screws provide a high resistance to shear or torsional forces." *Id.* at 1:56–58. However, existing bone plating systems under high stress and loading conditions may have a locking plate hole that is distorted and allows the fixed angular relationship between the locking screw and plate to change. *Id.* at 2:20–22.

Weaver purports to resolve such deficiencies in its bone plating system. *Id.* at 2:28–29.

Figure 3, reproduced below, shows a side view of an exemplary bone plate. *Id.* at 3:25.

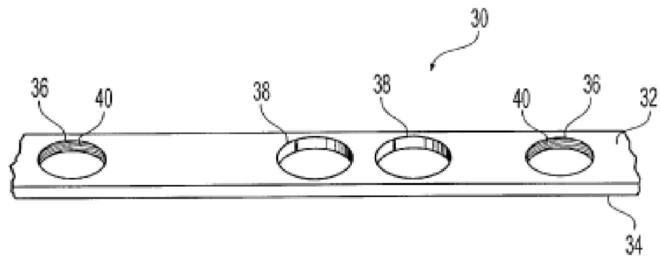


Fig. 3

Figure 3 shows bone plate 30 including first plate holes 36 and second plate holes 38. *Id.* at 4:45–46. Each first plate hole 36 has thread 40 that mates with thread 24 on head 22 of locking screw 20 (shown in Figure 2) to secure locking screw 20 to bone plate 30 at a temporally fixed angular orientation whereas second plate holes 38 are not threaded and receive non-locking screws 10 with non-threaded heads 12 (shown in Figure 1). *Id.* at 4:47–53. Weaver discloses that "first plate holes 36 are preferably conical in shape" and that "threads 40 on first plate holes 36 are also preferably double lead threads" which enable engagement "while maintaining a low profile." *Id.* at 5:1–5.

C. Ground 1: Anticipation of Claims 1–5, 9–14, and 17 by Slater

Petitioner contends, Slater discloses all elements of claims 1–5, 9–14, and 17, and thus anticipates those claims under 35 U.S.C. § 102(b). Pet. 14. To support its contention, Petitioner directs our attention to the foregoing disclosures of Slater and provides a detailed claim analysis addressing how each element of claims 1–5, 9–14, and 17 is disclosed by Slater. Pet. 14–36

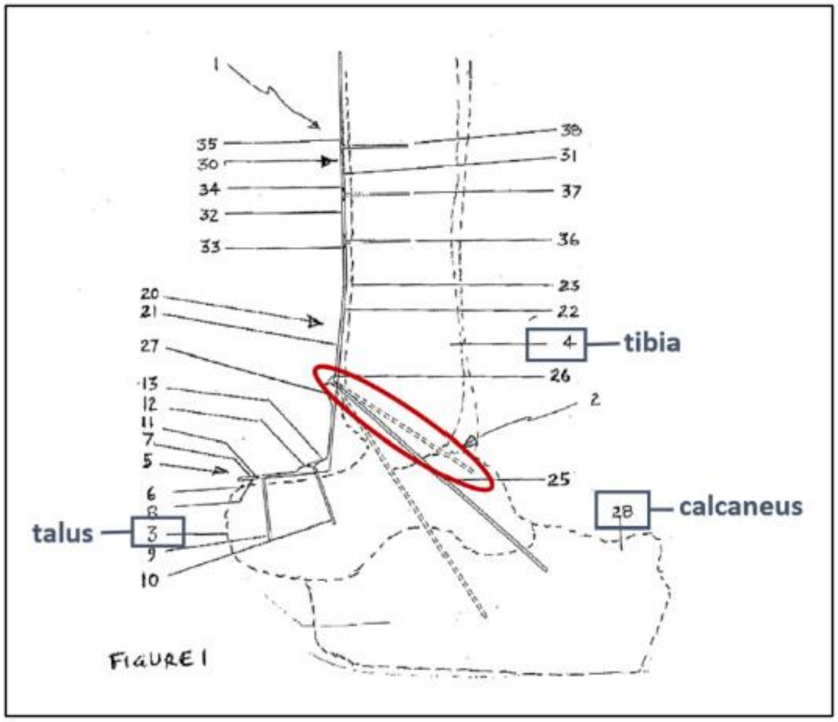
(citing Ex. 1002 ¶¶ 100–160). Patent Owner raises multiple counterarguments. PO Resp. 24–45.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–14, and 17 are anticipated by Slater. Our analysis follows.

1. Petitioner's Contentions

Petitioner first contends that, if claim 1's preamble is limiting, Slater discloses a system for securing two discrete bones together across a joint between the two bones. Pet. 16.[2] In support, Petitioner directs our attention to its annotated Figure 1 of Slater, reproduced below, which shows "a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines)." Pet. 15; Ex. 1005, 9:28–30.

[2] We need not decide whether the preamble is limiting because a system for securing two bones is disclosed in Slater. Moreover, although other portions of claim 1 might limit it to a system for securing two (and only two) bones, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.

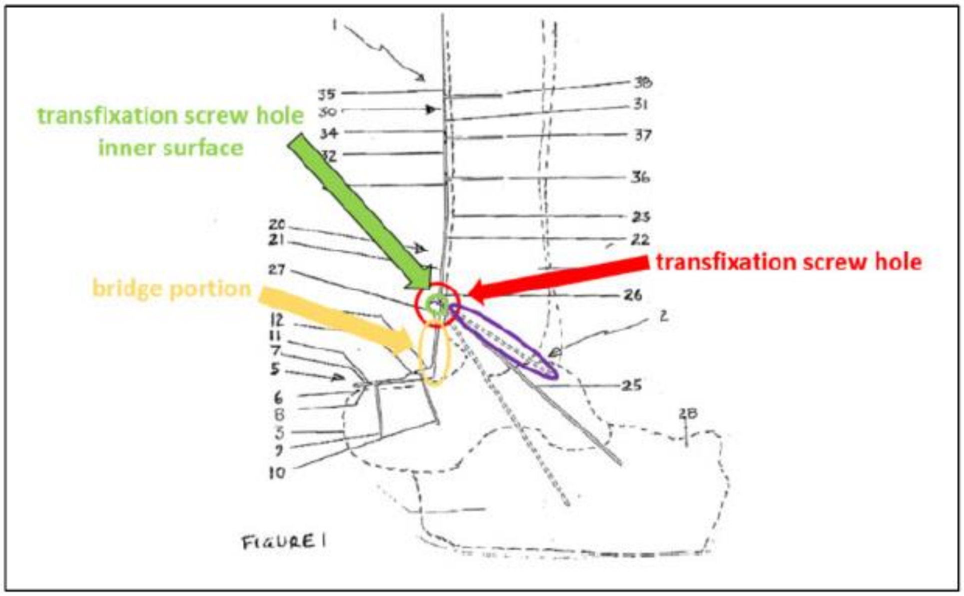


Id. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* With reference to the figure above, Petitioner asserts,

> Figure 1 of Slater illustrates (1) a fusion plate 1 being used to secure three discrete bones (tibia 4, talus 3, and [calcaneus] 28) across two joints and (2) an alternate embodiment where fusion plate 1 is used to secure two discrete bones (tibia 4 and talus 2, within the oval annotated into Figure 1 [above]) together across a single joint between the two bones.

Pet. 15 (citing Ex. 1005, 6:17–7:2, 8:13–28, 11:1–4, 12:3–10, 13:5–9, 14:1–8). Petitioner supports this interpretation of Slater with Dr. Gall's testimony. Ex. 1002 ¶ 102.

Next, Petitioner contends that Slater discloses claim 1's transfixation screw hole and transfixation screw limitations. Pet. 22–25. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



Id. at 23–24. Petitioner's annotation to Figure 1 identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). *Id.* (citing Ex. 1002 ¶ 113). According to Petitioner, "Figure 1 shows three separate exemplary angles for transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3)." *Id.* (citing Ex. 1002 ¶ 113); Ex. 1005, Fig. 1.

Petitioner contends that Slater discloses a transfixation screw with a head and shaft as claimed. Pet. 24–25. Again, referencing Slater's Figure 1, Petitioner contends that Slater discloses a screw configured to contiguously extend through a first bone (tibia 4), through a joint (2), and into a second bone (talus 3). *Id.* (citing Ex. 1005, Fig. 1, 11:19–25, 13:21–24; Ex. 1002 ¶ 114). For claim 1's recitation about the screw being configured "so as to absorb tensile load" and "transferring the tensile load" from the second bone

through the screw into the head and bridge, Petitioner contends that Slater satisfies those elements as well. *Id.* According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the talus through the screw into the screw head and plate's bridge portion as claimed. *Id.* Petitioner explains that "[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between." *Id.* (Ex. 1002 ¶ 114; Ex. 1005, 12:32–13:3). Petitioner additionally provides testimony from Dr. Gall to support this same understanding of Slater's teachings and the functionality of Slater's plate when fixed to the tibia and talus as shown. Ex. 1002 ¶ 114.

2. Patent Owner's Response

Patent Owner contends that "nothing in Slater expressly or inherently discloses transferring the tensile load from the second bone through the fixation screw head and into the bridge portion of the plate." PO Resp. 39. Specifically, Patent Owner contends that Petitioner and Dr. Gall improperly assume that Slater discloses a "vise" configuration to transfer tensile load from the second bone, through the screw and into the bridge portion. *See id.* According to Patent Owner, and its declarant Mr. Sommers, Dr. Gall's assumption depends on the assumption that the threads of Slater's screw 70 would only engage the second bone (the talus) in Slater's two-bone embodiment, but Slater lacks any disclosure to support this assumption. *See id.* at 39–40 (citing Ex. 2002 ¶ 110; Ex. 2003, 44:21–45:15). Patent Owner argues that Slater does not expressly or inherently disclose Petitioner's

"vise" construct, and that Slater fails to disclose how an undisclosed embodiment using the vise approach would transfer tensile load. *Id.* at 40–41 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶ 112). Patent Owner further contends that Dr. Gall's opinion lacks citations of support to Slater, and any reliance on Slater's finite element analysis lacks support because the test data does not state how the transfixation screw was affixed or loaded, or how many bones it penetrated. *Id.* at 41–42 (citing Ex. 1002 ¶¶ 114, 154; Ex. 2002 ¶¶ 117–119; Ex. 2003, 92:24–93:7).

3. Petitioner's Reply

Petitioner responds that Slater discloses the "vise" configuration because it uses a lag screw "through an angled formation in the bone plate to cross a joint or joints where the screw head is in 'cooperation' with the screw hole," creating a well-known "lag effect" to compress bone parts and absorb tensile load. Pet. Reply 15–16 (citing Ex. 1002 ¶¶ 114, 134–136, 153–154; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1026 ¶¶ 121–123; Ex. 1027 ¶¶ 39–50; Ex. 1030, 68:17–70:3, 106:19–107:17; Ex. 2003, 46:23–48:4). Petitioner argues that Mr. Sommers conceded that you only want threads in the second bone, and described transfer of tensile load in the '608 patent in the same manner that Dr. Gall describes Slater transfers tensile load. *Id.* at 16–17 (citing Ex. 1002 ¶¶ 114, 154; Ex. 1027 ¶¶ 37, 39, 44, 47–48; Ex. 1030, 67:23–68:7, 70:16–19, 71:5–9, 74:6–25, 75:5–13, 77:14–22; Ex. 2003, 90:24–91:23). Petitioner also argues that "Slater describes in-vivo studies that ***confirm*** tensile load is transferred from the bone to the screw and to the bone plate." *Id.* at 17 (citing Ex. 1005, 17:14–20:26; Ex. 2003, 92:17–93:7; Ex. 1027 ¶ 49). According to Petitioner, Slater's testing simulated in vivo loading conditions

and show that "at least some tensile load is necessarily distributed from the angled screw formation to the bridge portion." *Id.* at 17–18 (citing Ex. 1005, 17:20–21, 19:1–6; Ex. 1027 ¶¶ 49–50; Ex. 1030, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. Analysis

Independent claim 1 recites

> the transfixation screw comprises . . . a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone *so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone,* through the screw into said head and said bridge portion.

Ex. 1001, 12:23–31 (emphasis added). Independent claim 11 recites

> the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, *enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge.*

Id. at 13:22–31. We will refer to these limitations collectively as the "transfer of tensile load" limitations. The parties dispute whether Slater expressly or inherently disclose these limitations.

We first address Petitioner's argument that Slater discloses a "vise" configuration, which relies on Petitioner's argument that Slater uses a lag screw with threads on its end that only engage the second bone in Slater's two-bone configuration. *See* Pet. 24–25 (citing Ex. 1002 ¶¶ 114, 154; Ex. 1005, 12:32–13:3); Pet. Reply 15–17 (citing Ex. 1002 ¶¶ 114, 134–136,

153–154; Ex. 1005, 5:28–6:10, 6:18-28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1026 ¶¶ 121–123; Ex. 1027 ¶¶ 37, 39–50; Ex. 1030, 67:23–68:7, 68:17–70:3, 70:16–19, 71:5–9, 74:6–25, 75:5–13, 77:14–22, 106:19–107:17; Ex. 2003, 46:23–48:4, 90:24–91:23). We are not persuaded by Petitioner's argument because Slater does not expressly or inherently disclose how its lag screw threads interact with the first and second bone. Slater's Figure 4 "shows an elevation view of a second screw type 70" having "a longer shank to increase depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone." Ex. 1005, 12:32–13:3. This description of screw type 70 in the *three*-bone configuration does not state that the screw *only* engages the third bone, the calcaneus bone, and describes the "majority of the shank" as "slid[ing] through" holes in the first two bones without stating that none of the threads engage a portion of, for example, the end of the second bone adjacent the third bone. *See id.* More importantly, even if this portion of Slater describes a *three*-bone embodiment where the threads only engage the third bone, Slater provides insufficient support for Petitioner's position that the threads of screw type 70 only engage the second bone in Slater's *two*-bone embodiment, which Petitioner relies on as the anticipatory embodiment of Slater. *See* Pet. 24–25; Ex. 1002 ¶ 114 (arguing that Slater's Figure 1 shows two-bone embodiment). Slater contains no details on this aspect of its alternative two-bone embodiment, such that the threads of the screw may engage the end of the first bone adjacent the second bone and still provide satisfactory results. At best, Petitioner and Dr. Gall's related testimony establish that it would have been desirable, and perhaps obvious, to have the

threads of screw type 70 only engage the second bone in Slater's two-bone embodiment to create a vise-like configuration that transfers tensile load as claimed, but that does not establish that Slater expressly or inherently discloses such an embodiment to satisfy the anticipation standard.

We next address Petitioner's reliance on Slater's finite element analysis tests. *See* Pet. Reply 16–18. Petitioner did not rely on this aspect of Slater in the Petition, and raised the argument for the first time in Reply. *Compare* Pet. 24–25, *with* Pet. 24–25; Reply 17–18. Setting aside the propriety of failing to rely on this aspect of Slater in the Petition, we are not persuaded by Petitioner's argument and evidence for two reasons. First, Petitioner appears to still rely on its argument that Slater discloses a "vise" configuration, and argues that the testing confirms the transfer of tensile load. *See* Pet. Reply 15–16 (relying in "vise" argument), 17 ("Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate."). Petitioner does not appear to argue that even if we find that Slater does not disclose the "vise" configuration and does not necessarily disclose screw threads that only engage the second bone, that the testing alone shows that Slater discloses the limitation. *See* Pet. Reply 15–18. Accordingly, we do not find the testing argument persuasive due to its link to arguments we find unpersuasive for the reasons discussed above.

Second, Patent Owner correctly points out that Slater provides inadequate information to conclude that the testing results apply to Slater's two-bone configuration such that we can conclude that Slater's two-bone embodiment results in the claimed transfer of tensile load to the plate's bridge. *See* PO Resp. 41–42 (citing Ex. 1002 ¶¶ 114, 154; Ex. 2002 ¶¶ 117–

119; Ex. 2003, 92:24–93:7). Slater's tests merely simulate the response of its plate to certain loads, and do not purport to show actual loading of the plate on a patient in either the three-bone or two-bone embodiments. Ex. 1005, 17:14–23 (referring to analysis of simulated in-vivo performance and "anticipated loadings" of the plate). Slater also emphasizes that the simulations only apply to "a plate of the particular type and geometry tested" and that "plates with different geometry and dimension . . . may result in different measured loadings and plate response" and "will be likely to have different load capacity results." *Id.* at 20:13–23. Based on the lack of detail as to how Slater's simulations would apply to its two-bone embodiment, and Slater's warning that the simulated results only apply to the specific plate tested, we agree with Patent Owner that Slater's simulated testing does not establish that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1 and 11.

Finally, for similar reasons, we find the testimony of Patent Owner's declarant Mr. Sommers more credible and persuasive than the testimony of Petitioner's declarant Dr. Gall. For example, Dr. Gall opines that Slater discloses a vise configuration, but fails to point to any portion of Slater disclosing that configuration with respect to the two-bone embodiment. *See* Ex. 1002 ¶ 114; Ex. 1027 ¶¶ 37–46. Again, this testimony may establish the desirability of such a configuration and that one of ordinary skill in the art, when using Slater's plate, may do so in the manner Dr. Gall proposes, but that does not establish that Slater expressly or inherently discloses a vise-like configuration due to threaded engagement with only the second bone in Slater's two-bone embodiment. We view the testimony of Mr. Sommers as more credible because it more accurately tracks Slater's disclosures. *See*

Ex. 2002 ¶¶ 57–58 (opining that Slater "does not describe whether there would also be threads" in the second of the three bones in the three-bone embodiment, in practice the threads may engage multiple bones, and Slater does not illustrate or describe how the screw would be used on a two-bone configuration), 81–83, 108–120 (opining that Slater fails to disclose the transfer of tensile load limitations).[3]

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1 and 11 and therefore does not prove, by a preponderance of the evidence, that Slater anticipates either of claim 1 or 11

Petitioner's challenge to dependent claims 2–5, 9–10, 12–14, and 17 as anticipated by Slater is substantially similar to its analysis of independent claims 1 and 11, which relies on Petitioner's predicate analysis on the independent claims. Pet. 26–32, 36. That analysis suffers from at least the same shortcomings discussed above for independent claims 1 and 11. Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–14, and 17 are anticipated by Slater.

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[3] We are also unpersuaded by Petitioner's arguments based on the alleged similarity between the description Mr. Sommers provides of how the '608 patent shows the transfer of tensile load and Dr. Gall's description of how Slater transfers tensile load. *See* Reply 16–17. It is hardly surprising, and largely irrelevant, that Petitioner's declarant would describe the prior art in a manner consistent with the Patent Owner or its declarant's description of the how the challenged patent works. That similarity alone does not establish that the prior art expressly or inherently discloses the limitation in question.

D. Ground 2: Obviousness of Claims 6 and 8 over Slater and Weaver

Petitioner contends that claims 6 and 8 are unpatentable for obviousness over Slater and Weaver. Pet. 37–39. Claims 6 and 8 depend from claim 1 and add, respectively, that transfixation screw hole or at least one attachment point includes features that lockably engage the transfixation screw head or locking bone screws. Ex. 1001, 12:48–50, 12:56–59. Petitioner alleges that those locking features are disclosed in Weaver and it would have been obvious to add them to Slater's plate to provide a more secure fixation between the screws and the plate. Pet. 37–39; Ex. 1002 ¶¶ 161–169. Petitioner otherwise relies on its anticipation analysis for claim 1 discussed above. Reply 37.

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to Slater and with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Slater and Weaver.

E. Ground 3: Anticipation of Claims 1–3, 6, 8–13, and 17 by Falkner

Petitioner contends that Falkner discloses all elements of claims 1–3, 6, 8–13, and 17, and thus anticipates those claims under 35 U.S.C. § 102(b). Pet. 39–58. To support its contention, Petitioner directs our attention to the foregoing discourses of Falkner and provides a detailed claim analysis addressing how each element of claims 1–3, 6, 8–13, and 17 is disclosed by Falkner. Pet. 14–36 (citing Ex. 1002 ¶¶ 170–233). Patent Owner raises multiple counterarguments. PO Resp. 46–56.

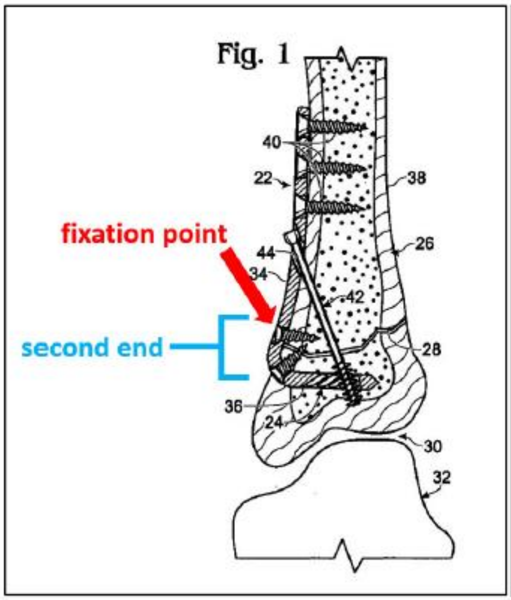
Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–13, and 17 are anticipated by Falkner. Our analysis follows.

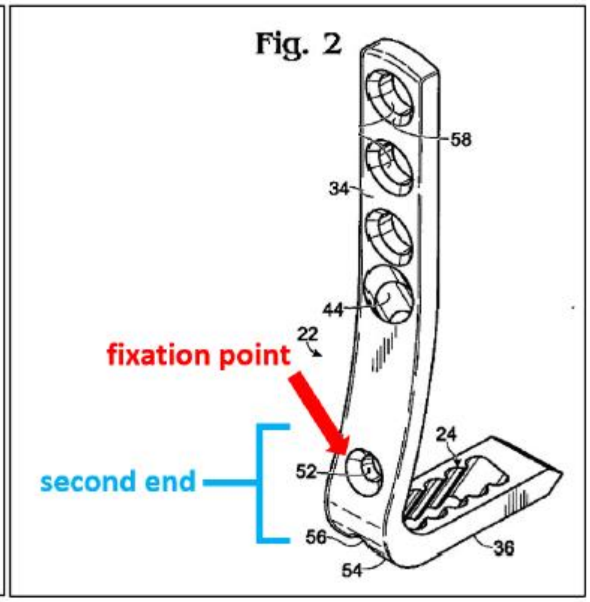
1. Petitioner's Contentions

We begin our analysis with Petitioner's contentions with regard to claim 1. Petitioner alleges that Falkner discloses claim 1's preamble. Pet. 39–40. According to Petitioner, although Falkner's Figure 1 shows a plating system for fixing a single bone having a fracture, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. *Id.* at 40 (citing Ex. 1006 ¶ 21). Petitioner also cites Falkner's disclosure that, in other examples, "***plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among them***." *Id.* (citing Ex. 1006 ¶¶ 27–29, 62).

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 41 (citing Ex. 1002 ¶ 175). And, Petitioner argues, "the inner surface [of the plate] would be configured to substantially conform with a geometry of the first discrete bone (tibia 26)." *Id.* at 42 (citing Ex. 1006 ¶ 23 and Ex. 1002 ¶ 176). According to Petitioner, this configuration would meet claim 1's "elongate spine" and "first end" limitations. *Id.* at 40–42.

For claim 1's "second end" limitations, Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.

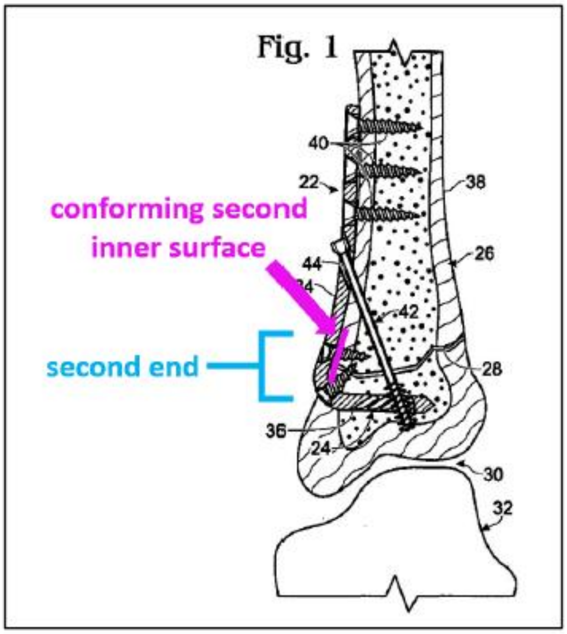




Pet. 43 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.*

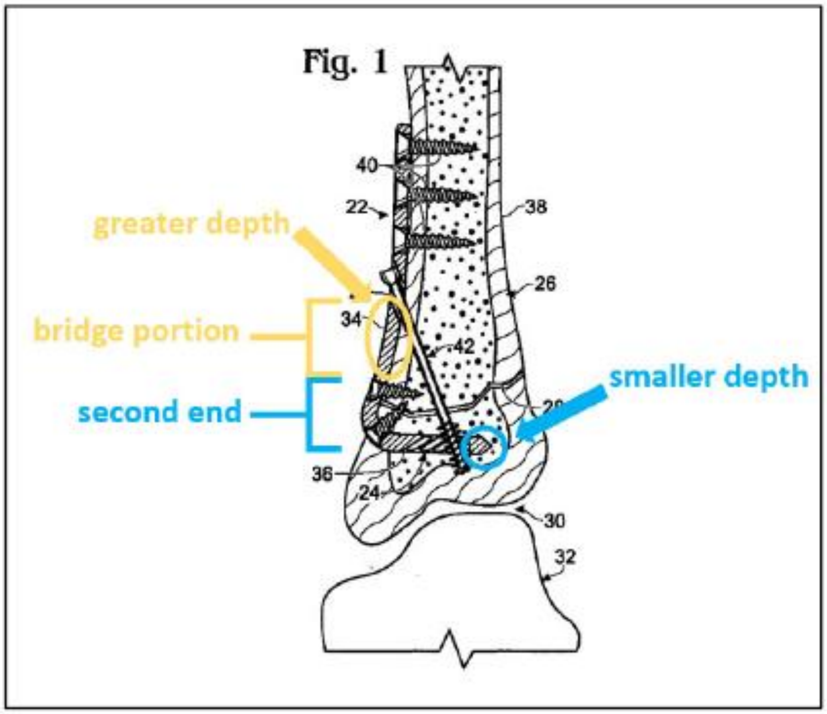
With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 43–44 (citing Ex. 1002 ¶ 177).

And, referencing another annotated version of Figure 1 (reproduced below), Petitioner contends that "the second inner surface would be configured to substantially conform with a geometry of the second discrete bone (talus 32)." *Id.* at 44–45 (citing Ex. 1002 ¶ 178).



Id. at 44; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner's plate attached to the tibia, including Petitioner's blue bracket designating the same alleged "second end," but here, Petitioner annotates (with purple arrow, line, and text) an alleged conforming "second inner surface." Pet. 44. Petitioner's position appears to be that this purple portion depicted in Figure 1 would be adapted and thus configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. *Id.*

Turning to claim 1's bridge portion and the requirement that the bridge portion have a depth or thickness greater than a portion of the first or second ends, Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 45–47. This annotated figure is reproduced below.



Id. at 46; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, above, shows the same plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval, bracketing, and text. Pet. 46. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" has a "greater depth." *Id.* This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as having a "smaller depth," which Petitioner highlights with a blue circle, arrow, and text. *Id.* From this, Petitioner argues that "at least a portion of the bridge portion has a thickness greater than at least a portion of the thickness of the second end." *Id.* (citing Ex. 1002 ¶ 181).

For the transfixation screw hole and transfixation screw limitations of claim 1, Petitioner cites Falkner's oblique opening (44) in external plate portion (34), and threaded fastener (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate's internal plate portion (36). Pet. 47–49. According to Petitioner, in a configuration where Falkner's plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* at 48. And, in that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred from the talus through the screw and into the bridge portion. *Id.* at 49 (citing Ex. 1002 ¶ 184). In support, Petitioner cites Falkner's teaching that "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." Pet. 49 (quoting Ex. 1006 ¶ 71).

2. Patent Owner's Response

Patent Owner makes three main arguments with regard to independent claims 1 and 11. PO Resp. 46–56. For purposes of this decision, especially given the parties' overlapping arguments, we focus on claim 1.

First, Patent Owner argues that Falkner fails to disclose a system for securing two discrete bones together across a joint between the two bones. *Id.* at 47–49. Patent Owner contends that Falkner's plate is not designed to secure the two discrete bones across a joint and further contends that "[t]o make a Falkner-type plate that crosses a joint would require extensive modification." PO Resp. 47–48.

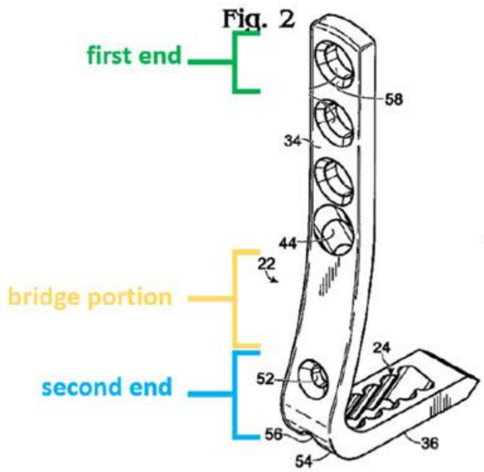
Second, Patent Owner argues that Falkner fails to disclose a "second end" that includes a "fixation point" and an "inner surface configured to substantially conform with a geometry of the second discrete bone" as required by the claims. *Id.* at 50–54. Patent Owner argues that what Petitioner identifies as the "second end" of Falkner's plate is inside the bone and therefore does not conform to the geometry of the second bone. *Id.* at 51 (citing Ex. 1006 ¶ 22). Patent Owner further contends that,

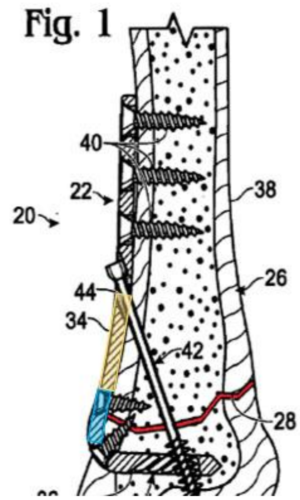
> With the interior portion of the Falkner blade-plate unable to conform to the geometry of the second discrete bone, the Petition relies on Dr. Gall, rather than the disclosure of Falkner, to conclude that "the plate 22 ***would have been*** placed across the joint 30 and the second inner surface ***would have been*** configured to substantially conform with a geometry of the second discrete bone (talus 32)." (Ex. 1002, ¶ 178 (emphasis added)). That something "would have been configured" is the hallmark of obviousness, and perhaps recognizing this after the fact, Dr. Gall at his deposition seemingly changed course and indicated that a Falkner plate spanning a joint would still include the portion that is interior to the bone. (Ex. 2003, 86:11–15). Therefore, Falkner fails to disclose a second end configured to "substantially conform with a geometry of the second discrete bone."

PO Resp. 51–52.

Third, Patent Owner contends that Petitioner's modified version of Falkner's plate does not have any portion configured to span across the bridge portion. *Id.* at 54–56. Patent Owner explains that even if the Falkner plate can be moved across the joint, the plate would cross the "second end", not the bridge portion. *See id.* at 54 ("the *Falkner* blade-plate 'bridge portion' that Petitioners rely upon would not cross the joint at all"). To illustrate that point, Patent Owner references and compares Dr. Gall's

annotated image of Falkner's figure 1, shown below on the left, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the right.





Id. at 55 (citing Ex. 1006 Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 224); Ex. 2002 ¶ 148 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as in would be applied to a bone. Ex. 1001 ¶ 8. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* at ¶¶ 9, 67. Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioners identify as the "second end." PO Resp. 55. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has identified, highlighted in blue, just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* (citing Ex. 2002 ¶ 149). Thus, according to Patent Owner, the Falkner plate does not cross the bone discontinuity in Figure 1.

3. Petitioner's Reply

In its Reply, Petitioner responds that "Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the [S]pecification 'may be positioned on and/or in any suitable bone(s) to span any natural or artificial discontinuity within a bone or between bones.'" Reply 20 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1028. Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes' testimony who believes that "Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***." Reply 21 (citing Ex. 1028, ¶¶19–20, 25–36). Instead, Petitioners cite to Dr. Holmes who describes a procedure whereby:

> surgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus" to help create a biomechanically stable joint for fusion. (Ex.1028, ¶¶31-32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Reply 21. Petitioner contends that Falkner "expressly enables a [person of ordinary skill in the art] to use its bone plate for joint fusion, and teaches all of the structural limitations set forth in the challenged claims." *Id.* at 22.

4. Patent Owner's Sur-reply

In its Sur-Reply, Patent Owner responds that Falkner does not disclose the modifications required to anticipate the challenged claim and instead, the Petitioner relied heavily on Dr. Holmes' testimony on how the

plate could have been modified. Sur-Reply 19. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that the theory of anticipation raised in the Petition is obviousness in disguise." *Id.* at 21. Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-Reply 21–24 ("the extensive modifications required for Falkner's plate to be used across a joint go beyond what reasonably could be anticipation")

5. Analysis

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. Petitioner's position does not prevail for at least the reasons set forth on pages 47–56 of the Patent Owner Response and pages 19–24 of the Sur-reply, which we adopt. In particular, we agree with Patent Owner that Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed. PO Resp. 48–49; Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured as claimed would apparently require at least some level of redesign or modification. Those might be simple, even arguably obvious, changes for the person of ordinary skill in the art in light of Falkner and its overall teachings, but Petitioner's challenge is based on anticipation. Indeed, Petitioner's and Dr. Gall's repeated invocation of how Falkner's plate, if

used in the hypothetical joint-spanning context, "would have been" configured rings of obviousness, not anticipation. *See, e.g.*, Ex. 1002 ¶ 178.

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But there is a dearth of detail about such a hypothetical plate's actual design. On this record, it appears to us that making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met (e.g., surfaces of the first and second ends that conform to a bone geometry, and a thicker bridge portion relative to the ends). The person of ordinary skill in the art might, for example, decide to conform some or multiple portions of the hypothetical bone plate to the exterior geometries of multiple bones, such as the tibia and talus. Such a design is even arguably suggested elsewhere in Falkner, where it discloses that bone plates "may be sized and shaped to conform to particular portions of a bone (or bones)" or "may be contoured generally to follow an exterior surface of a target bone (or bones)" (Ex. 1006 ¶¶ 33–34). But, here again, our concern is that such a theory drifts from anticipation—a doctrine still rooted in "strict identity"[4]—to obviousness.

Moreover, we note that Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate that appears to be close to the middle of the plate and characterizes that

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[4] *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002).

portion as a "second end." Pet. 43. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id.* at 46. Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its anticipation position, while purporting to modify other portions of that embodiment (e.g., contouring the plate to a particular bony geometry) in order to render it suitable for a different attachment across multiple bones.[5] Such picking and choosing is indicative of obviousness.

Regarding independent claim 11, Petitioner acknowledges that many of the limitations recited in independent claims 1 and 11 are "nearly identical" with exceptions accounted for in its analysis set forth in the Petition. Pet. 56–58. Those differences between claim 1 and 11 identified by Petitioner do not cure the deficiencies discussed above with regard to claim 1. Thus, for at least the same reasons as discussed with respect to claim 1, we are not persuaded on the current record that Falkner anticipates claim 11.

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[5] As a further example, Petitioner identifies opening (52) in Falkner's plate in Figure 1 as the alleged fixation point on a second end of the plate as claimed. Pet. 43. But, as described in Falkner, opening (52) and its corresponding bone screw is fixed on the *same side* of the bone discontinuity (fracture) as the plate portion Petitioner identifies as the plate's first end. Ex. 1006, Fig. 1. Inasmuch as a joint is simply another bone discontinuity in Falkner, Petitioner asserts, with minimal explanation, that a screw would have been placed through opening (52) to secure a second bone (e.g., talus) on the *opposite side* of the joint relative to the plate's first end when the plate is modified for use in this different context. *Id.* at 44; Ex. 1002 ¶ 177.

Petitioner's challenge to dependent claims 2–3, 6, 8–10, 12–13, and 17 as anticipated by Falkner relies on Petitioner's predicate analysis on the independent claims. Pet. 55–56, 58. That analysis suffers from at least the same shortcomings discussed above for independent claims 1 and 11.

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–13, and 17 are anticipated by Falkner.

F. Ground 4: Obviousness of Claims 4, 5, and 14 over Falkner and Arnould

Petitioner argues that dependent claims 4, 5, and 14 would have been obvious over Falkner and Arnould. Pet. 58–62. Petitioner's argument under Ground 4 relies on Petitioner's predicate anticipation challenge under Ground 3 for those claims from which claims 4, 5, and 14 depend. *Id.* Petitioner relies on Arnould under Ground 4 only for allegedly teaching certain transfixation angles encompassed by claims 4, 5, and 14.

We determine that Ground 4 suffers from at least the same shortcomings as discussed above for Ground 3. Also, Petitioner contends a person of ordinary skill in the art would have been motivated to modify Falkner's bone plate to provide a plate specifically for use with a metatarsophalangeal joint and, in so doing, select the transfixation angles disclosed in Arnould. Pet. 59–61. Petitioner's anticipation analysis of Falkner, however, focused on the plate of Falkner's Figure 1, allegedly designed to render it suitable for use with the tibia and talus. Petitioner provides no sufficient explanation as to how this plate would be now designed and configured for an entirely different set of bones and joint—the metatarsophalangeal joint—and still meet all the claim limitations of the underlying independent claims. *Id.* Accordingly, Petitioner fails to

demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Falkner and Arnould.

G. Ground 5: Obviousness of Claims 1–5, 9–14, and 17 over Arnould and Slater

Petitioner argues that claims 1–5, 9–13, and 16–19 would have been obvious over Arnould and Slater. Pet. 62–78. To support its contention, Petitioner directs our attention to its detailed claim analysis addressing how each element of claims 1–5, 9–13, and 16–19 is disclosed by Arnould and Slater. *Id.*; Ex. 1002 ¶¶ 248–309. Petitioner also contends that a person of ordinary skill in the art "would have been motivated to modify the bone plate of Arnauld with the thickened bridge portion of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." Pet. 67.

Patent Owner raises multiple counterarguments. PO Resp. 57–66. In particular, Patent Owner contends that thickening the portion of the Arnould plate Petitioner identifies as the bridge portion, "junction zone 14," would be contrary to the purpose of Arnould's disclosure. PO Resp. 59. Patent Owner further contends that Arnould in view of Slater fails to teach the elements of "a transfixation screw hole disposed along the spine." *Id.* at 60–63.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 would have been obvious by the combination of Arnould and Slater. Our analysis follows. For independent claims 1 and 11, like Petitioner, our analysis focuses on claim 1. Pet. 74–76 (relying substantially on analysis of claim 1 for claim 11).

1. Independent Claim 1

a. Whether there is Motivation to Combine Arnould and Slater

Petitioner contends that "Arnould discloses each and every element of independent claim 1 except" the element "which recites 'at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end.'" Pet. 63 (citing Ex. 1002 ¶ 248). For that missing limitation, Petitioner turns to Slater, which Petitioner argues discloses a thicker bridge portion. *Id*. Petitioner argues that a person of ordinary skill in the art "would have been motivated to modify the bone plate of Arnould with the thickened bridge portion of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." *Id*. at 67 (citing Ex. 1002 ¶ 257); *see also* Reply 26 (there is motivation to combine Arnould and Slater "to strengthen the plate in the area that experiences the highest stress—the portion near the MTP joint.") (citing Ex. 1002 ¶¶ 257, 304; Ex.1027 ¶¶ 57–59).

Petitioner also explains that "[w]ith the use of a plate bender, a surgeon can adjust even a thickened portion of an MTP plate to conform to the variable anatomy of the metatarsophalangeal joint." Reply 27 (citing Ex. 1028 ¶ 34). Moreover, Petitioner contends that

> *Arnould* expressly contemplates a surgeon modifying the angle between the metatarsal and phalangeal parts of the bone plate to accommodate varying degrees of dorsiflexion. Bending the plate at the bend line weakens the plate, so thickening the plate at the bend line would improve the strength of the *Arnould* plate.

Id. (citing Ex. 1008 ¶¶ 20, 38; Ex. 1027 ¶ 61).

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that the proposed

motivation is contrary to the disclosure of Arnould for two reasons. PO Resp. 58–60. First, thickening the specified portion in Arnould "would be contrary to the purpose of Arnould's disclosure" because "it is designed in a specific manner to allow a surgeon to bend the plate at that junction zone to conform the plate in situ to a patient's bone anatomy." PO Resp. 59–60; Ex. 1008 ¶ 20; Ex. 2002 ¶¶ 158–159; *see also* Ex. 2002 ¶ 160 (Arnould's "junction zone 14" is "purposely not strengthened to allow for bending by the surgeon at time of implantation.") (citing Ex. 1008 ¶ 38).

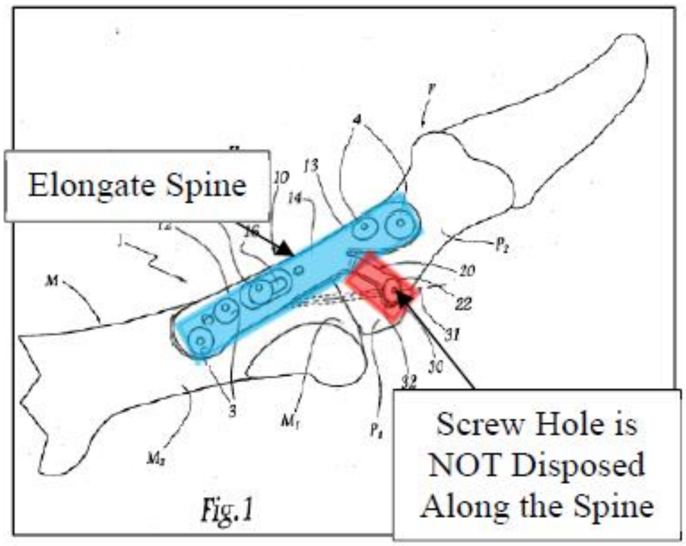
Second, there is no motivation to modify the plate in Arnould "[b]ecause the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest." PO Resp. 60. Rather, Arnould discloses that "the highest loading occurs in the cross-joint screw itself: 'this screw essentially, **<u>if not exclusively</u>**, takes up the bending stress generated during the patient's walking.'" PO Resp. 59–60 (quoting Ex. 1008 ¶ 6; citing Ex. 2002 ¶¶ 70, 173). "Because the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest, there would be no reason to modify that portion of the plate to accommodate additional stress as taught in Slater." *Id.* at 60.

b. Whether Arnould in view of Slater Fails to Teach a Transfixation Screw Hole Disposed Along the Spine

Claims 1 and 11 of the '608 Patent specify that the "transfixation screw hole [is] disposed along the spine" of the plate. Ex. 1001, cl. 1, 11. The Petition relies solely on Arnould for this element. Pet. 69.

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that Arnould in view of Slater fails to teach or suggest a transfixation screw hole to be deposed along

the spine. PO Resp. 60–62. The alleged transfixation screw hole of Arnould is a "through-hole 25 (at the end of leg 20[)] . . . [and] is not disposed on the spine, but part of a separate leg piece that extends off the spine." *Id.* at 60. The following annotated version of Arnould's Figure 1 illustrates that point.



Id. at 61; Ex. 1008, Fig. 1. The annotated version of Arnould's Figure 1, above, shows plate (1) having a plate body (10) attached to the metatarso-phalangeal bones and joint, and Patent Owner has highlighted in blue the plate's longitudinal body, which Patent Owner calls the "Elongate Spine." PO Resp. 61. In red, Patent Owner highlights leg (20), which extends downward from the longitudinal side of the plate body near the plate's midsection. *Id.* Patent Owner also adds an arrow identifying a screw hole at the end of the leg (20), which Patent Owner adds "is NOT Disposed Along the Spine." *Id.*

Arnould discloses that leg (20) "is meant to wrap around the bone and is located vertically below the plate body," which is evident with reference to Figure 1 above. Ex. 1008 ¶ 23; Ex. 2002 ¶¶ 163, 164. Furthermore, as noted by Patent Owner:

> Arnould fails to disclose or suggest disposing screw 30 along the spine; and there is no reason in view of Arnould to locate a transfixation screw hole along the spine as required by the claims of the '608 Patent because the explicit advantage of Arnould is that the leg and screw were moved off the spine to generate "a significantly higher capacity to resist bending stresses than the plate body due to its structure and **implantation zone**."

PO Resp. 61–62 (citing Ex. 1008 ¶ 6 (emphasis added); Ex. 2002 ¶ 165).

We have considered but are not persuaded by Petitioner's Reply argument that

> Patent Owner incorrectly re-writes "disposed along the spine" as "disposed on the spine," and improperly narrows the term "spine" to mean the center line of the plate. (POR, 60). The claim language nowhere equates the "elongate spine" with the center line of the plate.

Reply 27. Rather, we agree with Patent Owner that

> Something cannot be both along the body (or in the case of the claims, the spine) and below it. Petitioners also ignore the rest of claim 1, which requires that "the bridge portion [of the elongate spine] [be] configured to span across the joint," and that "a transfixation screw hole [is] disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends through the bridge portion at a trajectory . . . [.]" (Ex. 1001, cl. 1). *Given that leg 20 is located below the body of the plate and does not cross the joint, it cannot be the claimed bridge portion*.

Sur-reply 26 (emphasis removed; emphasis added).

c. Analysis of Remaining Claims

Petitioner's analysis of independent claim 11 as obvious over Arnould and Slater is essentially the same as its analysis of claim 1. Pet. 74–76. That

analysis suffers from at least the same shortcomings discussed above for claim 1. The same is true of Petitioner's analysis of dependent claims 2–5, 9–10, 12–14, and 17, which relies on Petitioner's predicate analysis on the independent claims. *Id.* at 70–76, 78.

2. Conclusion

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 would have been obvious over Arnould and Slater.

H. Ground 6: Obviousness of Claims 6 and 8 over Arnould, Slater, and Weaver

Petitioner argues that claims 6 and 8 would have been obvious over Arnould and Slater, in further view of Weaver. Pet. 78–79. Petitioner's reliance on Weaver here is substantially the same as for Ground 2—citing Weaver's screw locking features and reasons to add them. *Id.* Claim 6 and 8 depend, however, from claim 1 and Petitioner's challenge under Ground 6 presumes Petitioner's predicate success on Ground 5. *Id.* (asserting that "independent claim 1 is rendered obvious by Arnould in view of Slater" before turning to claims 6 and 8).

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to the combination of Arnould and Slater with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Arnould, Slater, and Weaver.

III. CONCLUSION

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 9–14, 17	102	Slater		1–5, 9–14, 17
6, 8	103	Slater, Weaver		6, 8
1–3, 6, 8–13, 17	102	Falkner		1–3, 6, 8–13, 17
4, 5, 14	103	Falkner, Arnould		4, 5, 14
1–5, 9–14, 17	103	Arnould, Slater		1–5, 9–14, 17
6, 8	103	Arnould, Slater, Weaver		6, 8
Overall Outcome				1–6, 8–14, 17

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6, 8–14, and 17 of the ’608 patent are not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01450
Patent 8,529,608 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*, concurring.

I concur that Slater does not anticipate claims 1–5, 9–14, and 17, and reach that result for the following additional reason.

Independent claims 1 and 11 recite a "transfixation screw hole comprising *an inner surface configured to direct the transfixation screw* through the transfixation screw hole *such that* the transfixation screw extends through the bridge portion *at a trajectory configured to* pass through a first position on the first discrete bone, a portion of the joint, and a second

position on the second discrete bone once the plate is placed across the joint." A dispute between the parties is whether the claim recitation for "an inner surface configured to direct the transfixation screw . . . *at a trajectory*" is taught by Slater.

To that point, Petitioner contends that Slater identifies openings 26 and 93 that "each receive a fixation screw that passes through those openings so that the screw is implanted at an angle." Pet. 23 (citing Ex. 1005, 11:19–21, 13:21–24, Figs. 1 and 7). More specifically, Petitioner contends that Slater's "transfixation screw hole (26 or 93) . . . comprises an inner surface (unnumbered in Slater's drawings) configured to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends through the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first discrete bone (tibia 4), a portion of the joint (2), and a second position on the second discrete bone (talus 3) once the plate (1 or 80) is placed across the joint." *Id.* at (citing Ex. 1002 ¶ 113; Ex. 1005, 11:19–25, 13:21–25).

In its Response, Patent Owner directs our attention to Figure 1 of Slater, and contends that this Figure "depicts, in phantom, the use of a screw that passes through the tibia and terminates in the talus." PO Resp. 10 (citing Ex. 2002 ¶ 55). "The hole that the screw 25 passes through is constructed in a manner that allows the angle of the screw to be modified as the plate is affixed to the ankle joint." *Id.* at (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). "This hole is described as 'slotted,' meaning that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles."

Id. at 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8); *see also* Ex. 1005, 16:28–30 ("One significant advantage of the plate described is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required."), Fig. 1.

Furthermore, Patent Owner notes that Slater "provides no detail regarding the structure of the inner surface of the hole" because a surgeon using Slater's plate "determines the path in situ with a range of options available." PO Resp. 34–35 (citing Ex. 1005, Fig 1; Ex. 2002 ¶ 97). That is, "Slater describes a plate that intentionally allows for varied angles through the same hole." *Id.* at 35–36 (citing Ex. 1005, 16:28–30 ("[o]ne significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required"); Ex. 2002 ¶ 103)). Patent Owner contends that, because the hole identified by Petitioner as Slater's transfixation screw hole allows for varied angles through the same hole, Slater fails to disclose a transfixation screw hole having "an inner surface configured to direct the transfixation screw through the transfixation screw hole . . . at a trajectory," where "trajectory" is properly interpreted to mean an "allowable fixed angle relative to the neutral bending axis of the joint." PO Resp. 18–20, 34–36.

In its Reply, Petitioner contends that Patent Owner's suggestion that "trajectory" limits the challenged claims to a single, fixed angle is "unsupported by the intrinsic evidence." Reply, 4. Specifically, Petitioner contends that

> The claims recite only that the claimed "trajectory" is the transfixation screw trajectory, and that such trajectory is configured to pass through "a first position on the first [discrete] bone[, a portion of the joint,] and a second position on the second [discrete] bone" once the plate is placed across the joint.

> (EX1001, cls. 1, 11). *There is a wide range of angles at which this can be achieved, not just one fixed angle*. (EX1001, cl. 4; EX1027, ¶11)).

Reply, 2 (emphasis added). Petitioner further contends that "the inner surface of the transfixation screw hole does not, alone, determine the precise angle of the trajectory," as "the size, shape, and geometry of the screw also determine what angles the trajectory may have." *Id.* at 3 (citing Ex. 1027 ¶¶ 12–13).

Moreover, Petitioner contends that "Patent Owner's reliance on the 'neutral bending axis' as a point of reference for 'trajectory' is nonsensical" because "the neutral bending axis of a particular joint may shift depending on the position of the bone plate and the loads exerted on that joint" and, thus, "the 'trajectory' cannot be known by analyzing a bone plate or system alone." *Id.* at 3 (citing Ex. 2002 ¶ 39).

I begin this analysis by clarifying that I understand Patent Owner's position to be that the "inner surface of the transfixation screw hole" is not a hole configured to allow a screw to be inserted into a bone at a plurality of angles, but that the language of the claim requires a configuration that achieves a screw hole that directs a screw at a particular angle (or "trajectory"), where that angle may be configured within a certain range. PO Resp. 20 (citing Ex. 2002 ¶ 96; Ex. 1001, 6:25–30). Thus, the dispute between the parties is whether a singular "inner surface of the transfixation screw hole" may be configured to operate so as to accommodate a range of angles, for example, in the same manner that Slater's oblique screw portal allows for screws to be inserted at varied angles through the same hole. *Id.*; Ex. 1002 ¶ 102 ("One significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to

incorporate more joints into the arthrodesis as required.") (quoting Ex. 1005, 16:28–30); Ex. 2002 ¶ 103 ("I agree with Dr. Gall that *Slater* teaches a screw hole that allows a screw to be inserted at a wide range of angles").

With that important distinction in mind, I consider Patent Owner's contention that the term "trajectory" as used in the challenged claims means an "allowable fixed angle relative to the neutral bending axis of the joint." PO Resp. 18–20. Here, I note that the challenged claims themselves define what angles are "allowable." That is, an allowable angle for the transfixation screw is an angle that directs the screw "through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone." Ex. 1001, claim 1; *see also id.* at claim 11 ("through a first position on the first bone and a second position on the second bone").

Regarding Patent Owner's inclusion of the phrase "relative to the neutral bending axis of the joint" in its proposed construction of "trajectory," I recognize that the specification makes constant reference to the "neutral bending axis" and its relationship to the trajectory is defined by the disclosed transfixation screw hole. *See e.g.* Ex. 1001, 1:46–49 ("the trajectory may be configured to cross a neutral bending axis of the joint once the plate is placed across the joint"); *id.* at 2: 42–46 ("the inner surface of the transfixation screw hole in the plate may direct the transfixation screw along a trajectory that crosses a neutral bending axis of the joint"); *id.* at 5:53–57 ("When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show in FIG. 2), a 'tension band' construct is created that puts transfixation screw 150 under tension when joint 106 flexes."). I also recognize Dr. Gall's and Mr. Sommer's statements explaining that the axis of the bone plate may generally approximate the

direction of the neutral bending axis of the joint. Ex. 1002 ¶ 118; Ex. 2002 ¶ 94. Furthermore, later dependent claims, when accounting for the precise angles recited by those claims, expressly recite angles measured from the neutral bending axis of the joint. *See e.g.* Ex. 1001, claim 5 ("herein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis."). However, with regard to independent claims 1 and 11, I again find that the express recitation of "once the plate is placed across the joint" provides adequate basis for determining how a trajectory is defined, especially in view of the Dr. Gall's and Mr. Sommer's testimony, summarized above.[6] Ex. 1001, claims 1, 11; Ex. 1002 ¶ 118; Ex. 2002 ¶ 94.

The dispositive question is whether the recited transfixation screw hole is configured to direct the transfixation screw at a trajectory that is a fixed angle or is configured to allow for "adjustable orientation" based on "a predetermined allowable angular range" such as opening 26 of Slater, identified by Petitioner as the transfixation screw hole. Pet. 22; Ex. 1005, 12:23–25, 11:21–22. Here, I first note the specification of the '608 patent does not describe a plate having a hole identified as a transfixation screw hole that would accommodate insertion of a screw at a plurality of angles through the same hole. Rather, the specification repeatedly describes the

[6] I also note that our express determination of whether a trajectory should be measured from an elongate axis, neutral bending axis of the joint, or otherwise, is unnecessary as such a determination would not affect the outcome of our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999)))

disclosed plate system as having a transfixation screw hole where it is the inner surface of that hole that is configured to direct a screw at a trajectory, which, according to Mr. Sommers, is language a person of ordinary skill in the art would understand to describe a degree of precision around a single fixed angle. Ex. 1001, 1:26–45, 2:8–14, 2:42–46; Ex. 2002 ¶¶ 50, 95, 97; PO Resp. 18–19. For example, the specification describes how "increased plate thickness around transfixation screw hole 102 may also enable transfixation screw hole 102 *to be machined* into bone plate 100 *at an angle* relative to the top surface of bone plate 100." Ex. 1001, 8:47–52 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:46–47; 6:19–33. By comparison, other holes in the disclosed plates are not disclosed with the same level of effort toward precision when describing the trajectory of a screw. Indeed, the specification of the '608 patent even includes a description of an oblong opening such as the one found in Slater, described as compression hole 132 and serves the purpose of tightening bones so as to "to press together at the interface of joint 106." *Id.* at 8:53–9:26. Taken together, the specification, when read as a whole, describes plates with a transfixation screw hole configured at a single trajectory selected to achieve the functional objectives of the plate, namely, joint fusion, where that single trajectory is preferably between 30 and 70 degrees, and more preferably, 50 degrees. *Id.* at 6:19–33. Petitioner's fails to direct us to any example or other disclosure to support its alternative interpretation, namely, a plate configured with a transfixation screw hole configured to permit the placement of a screw at a plurality of trajectories or angles.

Second, other dependent claims support the interpretation of a trajectory configured at a fixed angle. Claim 2, for example, recites that the "central axis of the inner surface of the transfixation screw hole defines the trajectory," a distinguishing feature as compared to the device in Slater that I will discuss here by way of comparison. Ex. 1001, 12:32–36. Figure 1 of Slater depicts, in phantom, the use of screw 25 that passes through the tibia and terminates in the talus. PO Resp. 10 (citing Ex. 2002 ¶ 55). The hole that screw 25 passes through is oblique[7] and allows the angle of the screw to be modified as the plate is affixed to the ankle joint. *Id.* (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21-22). In other words, the oblong hole of Slater is specifically designed to not have a central axis that defines the screw trajectory. (Ex. 2002, ¶ 124); *see also* Ex. 2002 ¶ 98 (Figure 1 of Slater "does not detail anything at all regarding the structure of [the 'inner surface' of the transfixation screw hole], much less demonstrate the hole has an 'inner surface configured to direct the transfixation screw . . . at a trajectory.'")

Claim 4 includes an allowable range between 30 and 70 degrees for the trajectory. Claim 4, however, depends from claim 2, and therefore requires the central axis of the screw hole to define the trajectory of the

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[7] It is undisputed that the hole identified by Petitioner as the transfixation screw hole is oblong. As noted by Patent Owner, this hole is described as "slotted," which means "that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles." PO Resp. 11 (citing Ex. 2002, ¶ 56; Ex. 1005, 24:4-8). Likewise, Dr. Gall recognizes the same hole as the transfixation screw hole of Slater and describes it as an "oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required." Ex. 114; Ex. 1005, 16:28–30.

screw between 30 and 70 degrees. Upon review of this claim structure for the ’608 patent, I agree with Patent Owner that a person of ordinary skill in the art would understand that, in the context of the intrinsic record, this means that any given plate has a single fixed angle, and that different plates could have a different fixed angle, with plates having single fixed angles in the range between 30 and 70 degrees. PO Resp. 20 (Ex. 2002 ¶ 96; *see also* Ex. 1001, 6:25–30). Here, I also credit Mr. Sommer’s explanation that a person of ordinary skill in the art would understand that to mean that a surgeon would be provided with a kit that includes multiple plates, each one with a single fixed angle of, for example, 50, 55, 60, 65 and 70 degrees. Ex. 2002 ¶ 96; Sur-Reply, 4. Moreover, claim 5 further limits the trajectory of claim 4 to “a transfixation angle of about 50 degrees measured from the neutral bending axis.” Ex. 1001, cl. 5. Claim 6 further limits claim 1 and requires that “the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw,” and that engagement of the screw head and screw hole would inherently constrain the configuration of the screw hole to a particular angle. Thus, each of dependent claims 2–6 further limit claim 1 along the lines of a single “trajectory” and are more specifically directed to plates configured with a screw hole that defines a single trajectory.

Finally, while the term “trajectory” used in isolation may not necessarily connote a fixed angle, the assessment here is whether the independent claim’s recitation of an inner surface of a screw configured to direct a screw *at a trajectory* is describing a fixed angle, and more specifically, describing a screw hole configured to direct a screw at a single trajectory. In view of the claim structure of independent claims 1 and 11,

the content of the specification, and testimony of Mr. Sommer's, summarized above, I determine it does. The claims expressly require a transfixation screw hole that itself is "configured to direct the transfixation screw through the transfixation screw hole . . . at a trajectory," which in context of the claim itself indicates that a screw hole directs the trajectory of the screw, even if other factors may also influence the trajectory. *Cf*. Reply 3–4. In other words, we agree with Patent Owner that "[a person of ordinary skill in the art] reading [claims 1 and 11] in light of the intrinsic record would understand that [the claim language describing the recited screw hole] means that the shape of the inner surface of the transfixation screw hole is such that it guides the screw at a fixed angle." PO Resp. 19; Ex. 2002 ¶ 95.

I recognize Petitioner's argument that "[w]hile Slater's transfixation screw hole allows the transfixation screw to be positioned within a predetermined range, once the screw is threaded into the bone, the screw trajectory, and thus the angle, is fixed," however, I am not persuaded. Reply 12. Petitioner insufficiently explains how the fixation of the angle of the screw trajectory by virtue of being inserted into a bone equates to the claim requirement that the inner surface of the transfixation screw hole directs the screw at a trajectory.

Petitioner's challenge to dependent claims 2–5, 9–10, 12–14, and 17 as anticipated by Slater is substantially similar to its analysis of independent claims 1 and 11, which relies on Petitioner's predicate analysis on the independent claims. Pet. 26–32, 36. That analysis suffers from at least the same shortcomings discussed here for independent claims 1 and 11.

In view of the above, I determine that Slater does not disclose "the transfixation screw hole comprising an inner surface configured to direct the

transfixation screw . . . at a trajectory." Slater's opening 26 is meant to be a variable angle hole and not an opening configured to direct a screw at a particular angle or trajectory. *See* Ex. 1005, 11:19–22 ("an angle within a predetermined allowable angular range"); *see also* Ex. 2003, 65:1–4 (Dr. Gall agreeing that each of the angles depicted by phantom screws shown in Figure 1 of Slater are achieved through the same screw hole 26). Accordingly, for this additional reason, I determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–14, and 17 are anticipated by Slater.

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Paper 46
Date: March 8, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01451
Patent 9,351,776 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges.*

Opinion by the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* SNEDDEN.

DECISION
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") and OsteoMed LLC ("Patent Owner"). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–6 and 8–13 ("Challenged Claims") of U.S. Patent No. 9,351,776 B2 ("the '776 patent," Ex. 1001) are unpatentable.

A. Background and Summary

Petitioner filed a Petition requesting an *inter partes* review of claims 1–6 and 8–13 of the '776 patent. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 5.

Following institution, Patent Owner filed a Response to the Petition (Paper 23, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 27, "Reply"), and Patent Owner filed a Sur-Reply (Paper 33, "Sur-Reply").

On December 15, 2023, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 42.

B. Related Matters

Petitioner has filed petitions for *inter partes* review in IPR2021-01450, IPR2021-01452, and IPR2021-01453 for related U.S. Patent Nos. 8,529,608; 9,763,716; and 10,245,085. Pet. 1–2; Paper 4, 1–2. The parties indicate that the '776 patent is asserted against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.) and in *OsteoMed*

LLC v. Wright Medical Technology, Inc., Case No. 1:20-cv-1621 (D. Del.). *Id.*

Petitioner has also filed petitions for *inter partes* review in IPR2022-00189, IPR2022-00190 and IPR2022-00191 for U.S. Patent Nos. 8,529,608, 9,351,776 and 9,763,716, respectively.

C. The '776 patent (Ex. 1001)

The '776 patent discloses a "system for securing bones together across a joint." Ex. 1001, Abstract. The system may be used for reconstructing a joint that has been damaged due to bone or soft tissue trauma, in which a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint. *Id.* at 1:21–25.

The '776 patent discloses that its system has "the ability to tightly couple the bones of a joint together" by including a transfixation screw that is inserted across the joint through a bone plate. *Id.* at 2:31–35. More specifically, the '776 patent discloses that the presence of the transfixation screw across the joint "may increase the contact pressure on the bony interface of the joint, increasing the probability of a positive fusion." *Id.* at 2:46–50. According to the '776 patent, by having the transfixation screw passing from the first bone to the second bone, a "tension band" construct is created "that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint," thereby enhancing the integrity and reliability of the plate and increasing the load that the plate may support without increasing plate thickness. *Id.* at 2:54–61.

Figure 2, reproduced below, shows "a bone plate being used in conjunction with a transfixation screw to repair the failed metatarso-

phalangeal joint" and immediately below it is Figure 3, which shows "a more detailed isometric view of the bone plate." *Id.* at 3:9–14.

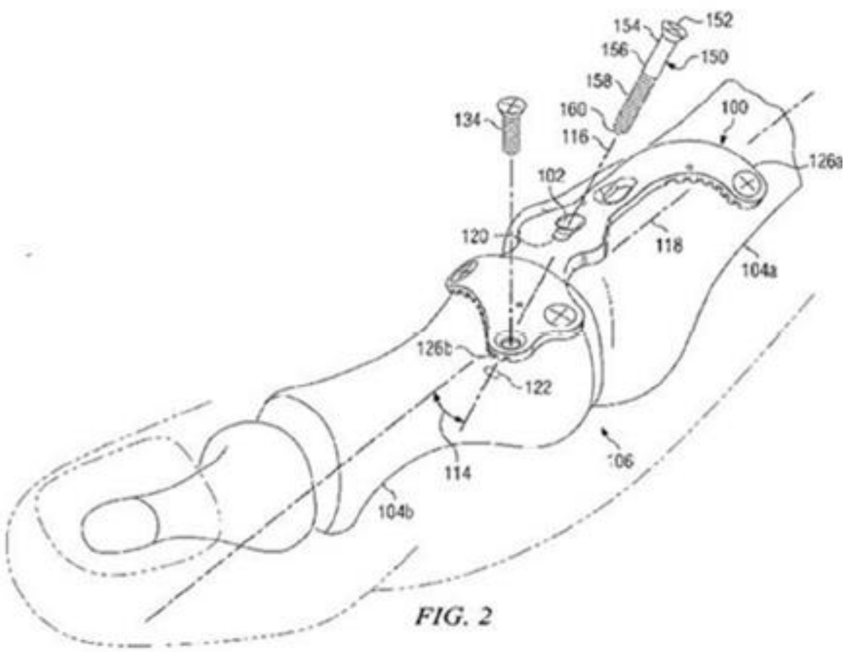


FIG. 2

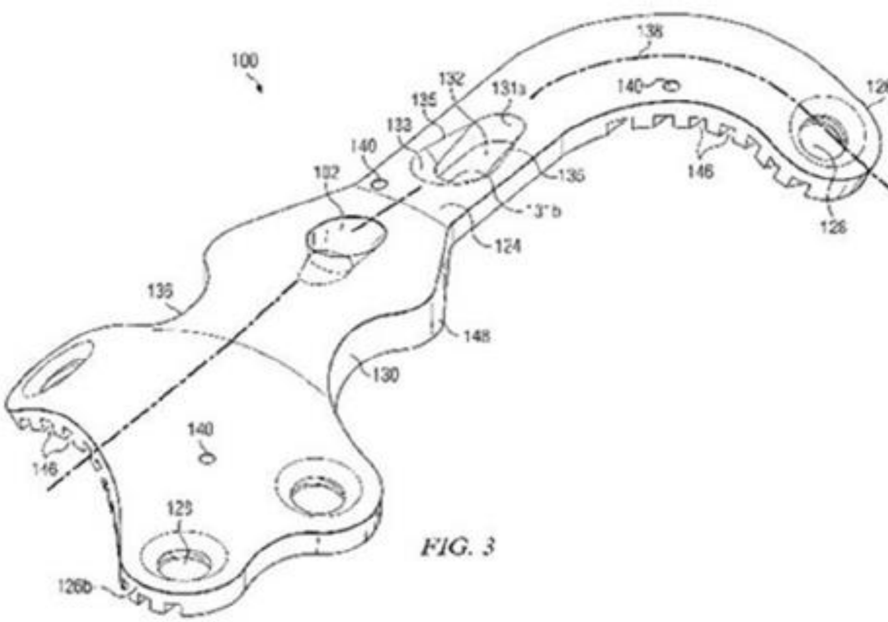


FIG. 3

Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id*. at 4:13–15. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b "in order to fuse joint 106." *Id*. at 4:26–30. Figure 3 shows bone plate 100 having elongated spine 124 and bridge portion 130 between first end 126a and second end 126b that can span across joint 106. *Id*. at 7:25–33. First end 126a includes attachment point 128 "for attaching first end 126a to bone 104a" and second end 126b includes another attachment point 128 "for attaching second end 126b to bone 104b." *Id*. The '776 patent discloses that bridge portion 130 "is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130" and may include thickened section 136 of bone plate 100 "to increase the bending strength of bridge portion 130." *Id*. at 8:9–16.

D. Illustrative Claims

Independent claims 1 and 10, reproduced below, are illustrative of the claimed subject matter of the '776 patent.

> 1. A system for securing two discrete bones together across a joint between the two bones, comprising:
>
> an elongate spine having:
>
> a first end comprising:
>
> at least one fixation point for attaching the first end to a first discrete bone on a first side of an intermediate joint; and
>
> a first inner surface configured to substantially conform with a geometry of the first discrete bone;
>
> a second end comprising:
>
> at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and

a second inner surface configured to substantially conform with a geometry of the second discrete bone; and

a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint, at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end; and

a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends the bridge portion at a trajectory configured to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone once the plate is placed across the joint; and

a transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion.

10. A plate for securing two discrete bones together across an intermediate joint, comprising:

an elongate spine having:

a first end comprising:

at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and

a first inner surface configured to substantially conform with a geometry of the first bone;

a second end comprising:

at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and

> a second inner surface configured to substantially conform with a geometry of the second bone; and
>
> a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint; and
>
> a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge, wherein at least a portion of said bridge portion and said transfixation screw hole has a depth greater than at least a portion of said first and second ends.

Ex. 1001, 11:64–12:36, 13:3–14:4.

Claims 2–6, 8, and 9 depend from independent claim 1. *Id.* at 12:37–54, 12:60–13:2. Claims 11–13 depend from independent claim 10. *Id.* at 14:5–16.

E. Evidence

Petitioner relies upon information that includes the following.

Ex. 1005, Slater, WO 2007/131287 A1, published Nov. 22, 2007 (“Slater”).

Ex. 1006, Falkner, Jr., U.S. 2005/0171544 A1, published Aug. 4, 2005 (“Falkner”).

Ex. 1007, Arnould, EP 1897509 B1, published Mar. 12, 2008.

Ex. 1008, Translation of EP 1897509 B1 (“Arnould”).

Ex. 1009, Weaver et al., US 6,623,486 B1, issued Sept. 23, 2003 (“Weaver”).

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1027) and Dr. George B. Holmes, Jr. (Ex. 1028) to support its contentions.

Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

F. Asserted Ground of Unpatentability

Petitioner asserts that claims 1–6 and 8–13 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–5, 9–13	102	Slater
2	6, 8	103	Slater, Weaver
3	1–3, 6, 8–12	102	Falkner
4	4, 5, 13	103	Falkner, Arnould
5	1–5, 9–13	103	Arnould, Slater
6	6, 8	103	Arnould, Slater, Weaver

II. ANALYSIS

A. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner takes the position that "[t]here are no claim terms in the Challenged Claims that require construction" and that Petitioner has

"applied the ordinary and customary meaning of each claim term." Pet. 8–9 (*citing Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)).

Patent Owner contends that the term "trajectory" as used in the Challenged Claims "means a fixed angle relative to the neutral bending axis of the joint." PO Resp. 18. Patent Owner's proposed construction is relevant to Ground 1 and our discussion below regarding whether Slater is anticipatory.

Having considered the parties' positions and evidence of record, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

B. Summary of Cited Prior Art

1. Summary of Slater (Ex. 1005)

Slater relates to an ankle fusion plate for fusion of the anterior ankle. Ex. 1005, 1:6–7. Slater discloses that orthopedic devices can repair diseased bones and bone fractures. *Id.* at 1:21–22. Slater explains that bones that have been fractured must be kept together for lengthy periods of time to permit recalcification and bonding. *Id.* at 3:1–3. According to Slater, internal fixation techniques require "the fracture be stable axially, torsionally and rotationally." *Id.* at 3:19–25; 7:1–2. To achieve such objectives, Slater

discloses a fixation screw and plate design in which "the plate depth changes at different locations" so that "the depth at the beginning a[n]d end points of the L shaped contour [of the plate] over the ankle joint in the second region will be at it[s] maximum thickness." *Id.* at 8:27–34. Slater further discloses that "[t]he plate will taper at least one but preferably two different points of the plate" and that "[t]hese points will preferably resemble and conform to the typical geometry of the anatomical region." *Id.* at 9:3–4, 11–12.

Figure 1, reproduced below, shows a side elevation view of a plate attached via fixation screws "to an abbreviated ankle joint (dotted lines)." *Id.* at 9:28–30.

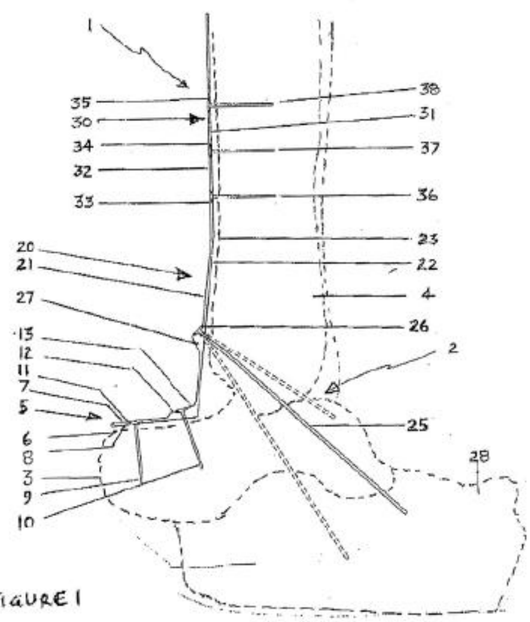


FIGURE 1

Figure 1 shows fusion plate 1 attached to the talus bone 3 and the tibial bone 4 that form ankle joint 2. *Id.* at 11:1–4. Fusion plate 1 includes portion 5 "disposed in a first plane which generally aligns with" anterior surface 6 of the talus bone 3 for fixation thereto. *Id.* at 11:5–8. Disposed in portion 5 are fixation screws 9 and 10 which pass through openings 11 and 12 of portion 5 to engage the talus bone 3. *Id.* at 11:8–9. Portion 20 of

fusion plate 1 has formation 27 with opening 26 disposed therein for allowing fixation screw 25 to pass therethrough. *Id*. at 11:18–21. "Formation 27 is configured so that [fixation] screw 25 is implanted at an angle within a predetermined allowable angular range" such that fixation screw 25 engages the tibia bone 4, the talus bone 3, and the calcaneus bone 28. *Id*. at 11:21–24. Portion 30 of fusion plate 1 includes openings 33, 34, and 35 which receive fastening screws 36, 37, and 38 to engage tibia bone 4. *Id*. at 11:27–31.

2. Summary of Falkner (Ex. 1006)

Falkner relates to systems for fixing bones using bone plates having apertures for retaining fasteners. Ex. 1006, Abstract. Falkner discloses that fixation of bone fractures can be problematic when these fractures are disposed near the ends of bones. *Id*. ¶ 4. Falkner purports to resolve past problems of achieving an interference fit that is tight enough to prevent slippage of a blade portion of the bone plate relative to an interlocking bone screw. *Id.* ¶ 6.

Figure 1, reproduced below, shows a sectional view of a system for fixing bones using a bone plate with a toothed aperture such that the bone plate is secured to a fractured bone. *Id.* ¶ 8.

Fig. 1

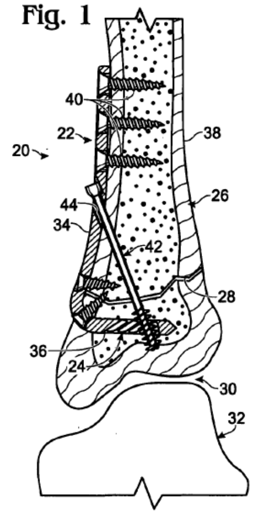


Figure 1 shows system 10 including bone plate 22 with toothed aperture 24 in which bone plate 22 "may be positioned on and/or in any suitable bone(s) to span . . . within a bone or between bones" such as on a region of the tibia bone 26 that spans fracture 28, as depicted. *Id.* ¶ 21. Thus, bone plate 22 may span joint 30 between tibia bone 26 and talus bone 32. *Id*. Bone plate 22 includes first plate portion 34 and second plate portion 36. *Id.* ¶ 22. Falkner discloses that bone screws 40 "may be placed into bone from any suitable number of openings of the bone plate." *Id.* ¶ 23. Threaded fastener 42 may extend through opening 44 and toothed aperture 42 of bone plate 22. *Id.* ¶ 24. Falkner discloses that bone plate 22 "may be sized and shaped to conform to particular portions of a bone (or bones)" and "may be thicker and thus stronger in regions where they may not need to be contoured, such as along the shaft of the bone." *Id.* ¶¶ 33, 35. Thickness of bone plate 22 "may be varied within" and a thicker portion may be provided to "increase structural stability." *Id.* ¶ 35.

3. Summary of Arnould (Ex. 1008)

Arnould "relates to an arthrodesis plate for a metatarsal-phalangeal joint." Ex. 1008 ¶ 1. Arnould discloses that a leg of its plate "allows the

plate to be attached to a lateral surface of the epiphysis of the phalanx." *Id.* ¶ 6. Arnould explains that "this leg is shaped so that its end hole can receive a long screw . . . which will extend both through the bone material of the phalanx and into the bone material of the metatarsal." *Id.* Thus, the "long screw extends lengthwise in a direction having an anteroposterior component, so that this screw essentially, if not exclusively, takes up the bending stresses generated during the patient's walking." *Id.*

Figure 1, reproduced below, shows a perspective view of an arthrodesis plate placed and fixed on a metatarsal-phalangeal joint locked by the plate. *Id.* ¶ 10.

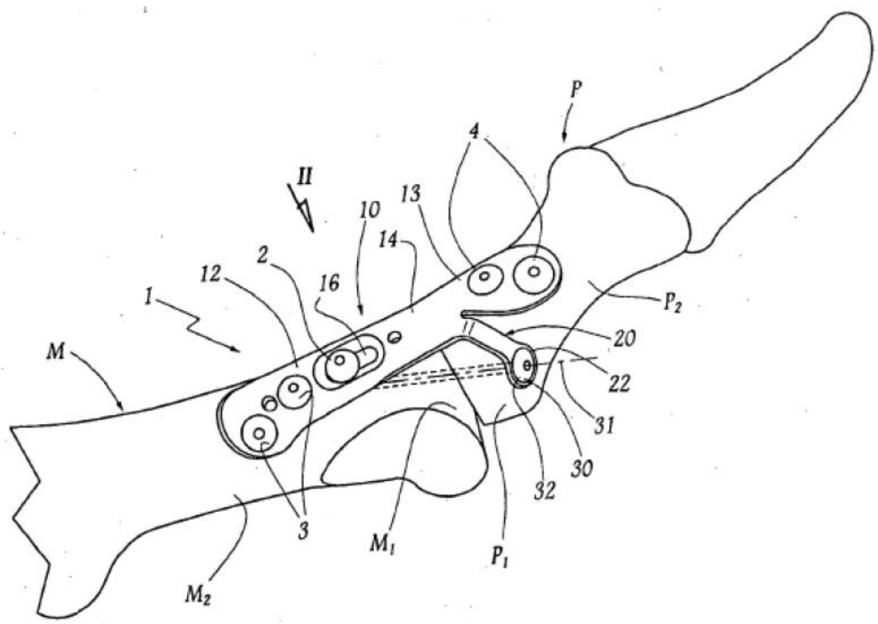


Fig. 1

Figure 1 shows arthrodesis plate 1 on a joint between metatarsal M and first phalanx P of a toe. *Id.* ¶ 11. Plate 1 includes plate body 10 and leg 20. *Id.* ¶ 13. Screws 3 and 4 secure opposite ends of plate body 10 via holes in the plate body to the bones as shown. *Id.* ¶¶ 33–34.

Leg 20 is provided with a through-hole for receiving screw 30 that has sufficient length to extend from the through-hole "into both the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, and possibly also into the metatarsal diaphysis M_2." *Id.* ¶ 26. Arnould discloses that "the leg 20 is bent downward relative to the plate body 10 along a bend line 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the leg and the phalangeal portion 13." *Id.* ¶ 24. Between the metatarsal portion 12 and phalangeal portion 13, there is a "zone 14" described as a "joint zone" or "junction zone." *Id.* ¶ 71. Arnould discloses that it is advantageous to include a junction zone with a "bending line 141" to allow "better adaptation of the plate body 10 to the anatomy of the joint when it is locked." *Id.* ¶ 20.

4. Summary of Weaver (Ex. 1009)

Weaver is directed to a bone plating system for fracture fixation, which includes a bone plate having plate holes for both locking and non-locking screws. Ex. 1009, 1:10–13. Weaver discloses that "[s]ecuring the screws to the plate provides a fixed angle relationship between the plate and screw and reduces the incidence of loosening" and such screws are called "locking screws." *Id.* at 1:46–49. According to Weaver, a known locking screw has threading on an outer surface of its head that mates with corresponding threading on the surface of a plate hole to lock the screw to the plate. *Id.* at 1:49–54. Weaver discloses that "locking screws provide a high resistance to shear or torsional forces." *Id.* at 1:56–58. However, existing bone plating systems under high stress and loading conditions may have a locking plate hole that is distorted and allows the fixed angular relationship between the locking screw and plate to change. *Id.* at 2:20–22.

Weaver purports to resolve such deficiencies in its bone plating system. *Id.* at 2:28–29.

Figure 3, reproduced below, shows a side view of an exemplary bone plate. *Id.* at 3:25.

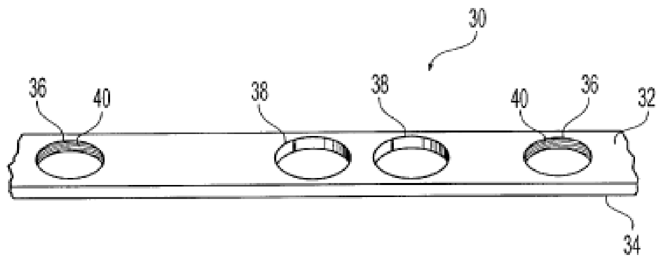


Fig. 3

Figure 3 shows bone plate 30 including first plate holes 36 and second plate holes 38. *Id.* at 4:45–46. Each first plate hole 36 has thread 40 that mates with thread 24 on head 22 of locking screw 20 (shown in Figure 2) to secure locking screw 20 to bone plate 30 at a temporally fixed angular orientation whereas second plate holes 38 are not threaded and receive non-locking screws 10 with non-threaded heads 12 (shown in Figure 1). *Id.* at 4:47–53. Weaver discloses that "first plate holes 36 are preferably conical in shape" and that "threads 40 on first plate holes 36 are also preferably double lead threads" which enable engagement "while maintaining a low profile." *Id.* at 5:1–5.

C. Ground 1: Anticipation of Claims 1–5 and 9–13 by Slater

Petitioner contends, Slater discloses all elements of claims 1–5 and 9–13, and thus anticipates those claims under 35 U.S.C. § 102(b). Pet. 16–36. To support its contention, Petitioner directs our attention to the foregoing disclosures of Slater and provides a detailed claim analysis addressing how each element of claims 1–5 and 9–13 is disclosed by Slater. *Id.* (citing

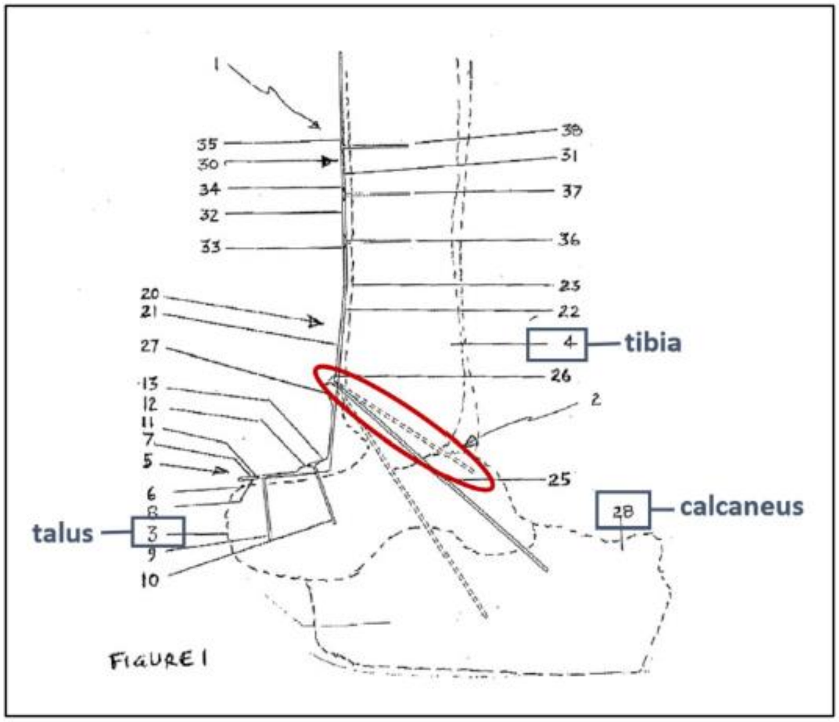
Ex. 1002 ¶¶ 112–165). Patent Owner raises multiple counterarguments. PO Resp. 24–45.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5 and 9–13 are anticipated by Slater. Our analysis follows.

1. Petitioner's Contentions

Petitioner first contends that, if claim 1's preamble is limiting, Slater discloses a system for securing two discrete bones together across a joint between the two bones. Pet. 16.[1] In support, Petitioner directs our attention to its annotated Figure 1 of Slater, reproduced below, which shows "a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines)." *Id.*; Ex. 1005, 9:28–30.

[1] We need not decide whether the preamble is limiting because a system for securing two bones is disclosed in Slater. Moreover, although other portions of claim 1 might limit it to a system for securing two (and only two) bones, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.

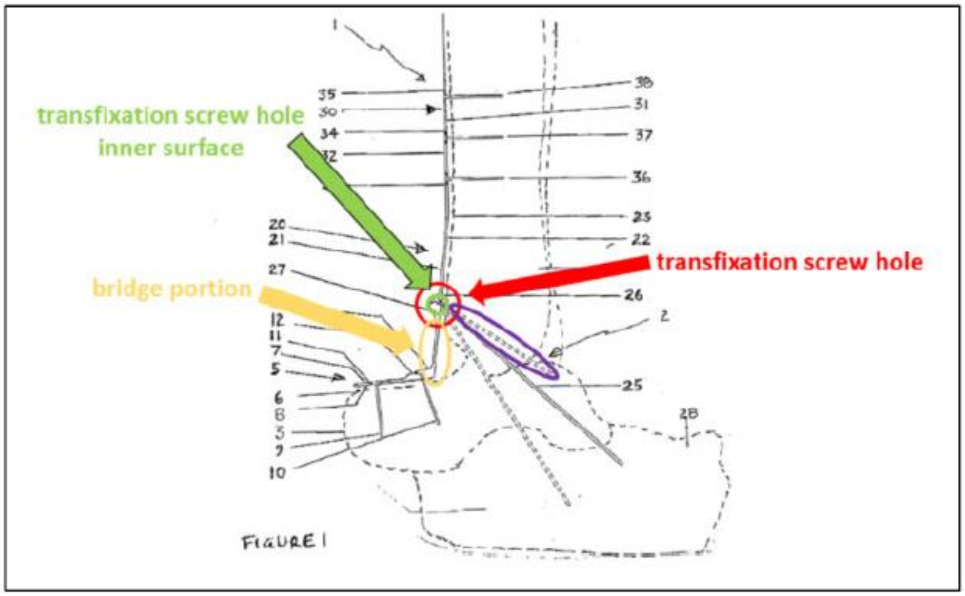


Id. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* With reference to the figure above, Petitioner asserts,

> Figure 1 of Slater illustrates (1) a fusion plate 1 being used to secure three discrete bones (tibia 4, talus 3, and [calcaneus] 28) across two joints and (2) an alternate embodiment where fusion plate 1 is used to secure two discrete bones (tibia 4 and talus 2, within the oval annotated into Figure 1 [above]) together across a single joint between the two bones.

Pet. *Id.* (citing Ex. 1005, 6:17–7:2, 8:13–28, 11:1–4, 12:3–10, 13:5–9, 14:1–8).

Next, Petitioner contends that Slater discloses claim 1's transfixation screw hole and transfixation screw limitations. Pet. 24–27. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



Id. at 23–24. Petitioner's annotation to Figure 1 identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). *Id.* (citing Ex. 1002 ¶¶ 123–124). According to Petitioner, "Figure 1 shows three separate exemplary angles for transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3)." *Id.*; Ex. 1005, Fig. 1.

Petitioner contends that Slater discloses a transfixation screw with a head and shaft as claimed. Pet. 26. Again, referencing Slater's Figure 1, Petitioner contends that Slater discloses a screw configured to contiguously extend through a first bone (tibia 4), through a joint (2), and into a second bone (talus 3). *Id.* (citing Ex. 1005, Fig. 1, 11:19–25, 13:21–24). For claim 1's recitation about the screw being configured "so as to absorb tensile load" and "transferring the tensile load" from the second bone through the screw

into the head and bridge, Petitioner contends that Slater satisfies those elements as well. *Id*. According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the talus through the screw into the screw head and plate's bridge portion as claimed. *Id.* Petitioner explains that "[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between." *Id.* (Ex. 1002 ¶ 125; Ex. 1005, 12:32–13:3). Petitioner additionally provides testimony from Dr. Gall to support this same understanding of Slater's teachings and the functionality of Slater's plate when fixed to the tibia and talus as shown. Ex. 1002 ¶ 125.

2. *Patent Owner's Response*

Patent Owner contends that "nothing in Slater expressly or inherently discloses transferring the tensile load from the second bone through the fixation screw head and into the bridge portion of the plate." PO Resp. 36. Specifically, Patent Owner contends that Petitioner and Dr. Gall improperly assume that Slater discloses a "vise" configuration to transfer tensile load from the second bone, through the screw and into the bridge portion. *See id.* According to Patent Owner, and its declarant Mr. Sommers, Dr. Gall's assumption depends on the assumption that the threads of Slater's screw 70 would only engage the second bone (the talus) in Slater's two-bone embodiment, but Slater lacks any disclosure to support this assumption. *See id.* at 36–37 (citing Ex. 2002 ¶ 107; Ex. 2003, 44:21–45:15). Patent Owner argues that Slater does not expressly or inherently disclose Petitioner's

"vise" construct, and that Slater fails to disclose how an undisclosed embodiment using the vise approach would transfer tensile load. *Id.* at 40–41 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶ 109). Patent Owner further contends that Dr. Gall's opinion lacks citations of support to Slater, and any reliance on Slater's finite element analysis lacks support because the test data does not state how the transfixion screw was affixed or loaded, or how many bones it penetrated. *Id.* at 41–42 (citing Ex. 1002 ¶¶ 125, 154; Ex. 2002 ¶¶ 117–119; Ex. 2003, 92:24–93:7).

3. *Petitioner's Reply*

Petitioner responds that Slater discloses the "vise" configuration because it uses a lag screw "through an angled formation in the bone plate to cross a joint or joints where the screw head is in 'cooperation' with the screw hole," creating a well-known "lag effect" to compress bone parts and absorb tensile load. Pet. Reply 13–14 (citing Ex. 1002 ¶¶ 125, 145–147, 160; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1026 ¶¶ 121–123; Ex. 1027 ¶¶ 34–45; Ex. 1030, 68:17–70:3, 106:19–107:17; Ex. 2003, 46:23–48:4). Petitioner argues that Mr. Sommers conceded that you only want threads in the second bone, and described transfer of tensile load in the '776 patent in the same manner that Dr. Gall describes Slater transfers tensile load. *Id.* at 14–15 (citing Ex. 1002 ¶¶ 125, 160; Ex. 1027 ¶¶ 42–43; Ex. 1030, 74:9–13, 90:24–91:23). Petitioner also argues that "Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate." *Id.* at 17 (citing Ex. 1005, 17:14–20:26; Ex. 2003, 92:17–93:7; Ex. 1027 ¶ 44). According to Petitioner, Slater's testing simulated in vivo loading conditions and show that "at least some tensile load is necessarily distributed from the

angled screw formation to the bridge portion." *Id.* at 17–18 (citing Ex. 1005, 17:20–21, 19:1–6; Ex. 1027 ¶¶ 44–45; Ex. 1030, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. Analysis

Independent claim 1 recites

> a transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone so *as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone*, through the screw into said head and said bridge portion.

Ex. 1001, 12:28–36 (emphasis added). Independent claim 10 recites

> the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, *enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge*.

Id. at 13:24–14:4. We will refer to these limitations collectively as the "transfer of tensile load" limitations. The parties dispute whether Slater expressly or inherently disclose these limitations.

We first address Petitioner's argument that Slater discloses a "vise" configuration, which relies on Petitioner's argument that Slater uses a lag screw with threads on its end that only engage the second bone in Slater's two-bone configuration. *See* Pet. 26–27 (citing Ex. 1002 ¶¶ 125, 160; Ex. 1005, 12:32–13:3); Pet. Reply 12–15 (citing Ex. 1002 ¶¶ 125, 134–136, 160; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1026 ¶¶ 121–123; Ex. 1027 ¶¶ 32, 34–45; Ex. 1030, 67:23–

68:7, 68:17–70:3, 70:16–19, 71:5–9, 74:6–25, 75:5–13, 77:14–22, 106:19–107:17; Ex. 2003, 46:23–48:4, 90:24–91:23). We are not persuaded by Petitioner's argument because Slater does not expressly or inherently disclose how its lag screw threads interact with the first and second bone. Slater's Figure 4 "shows an elevation view of a second screw type 70" having "a longer shank to increase depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone." Ex. 1005, 12:32–13:3. This description of screw type 70 in the *three*-bone configuration does not state that the screw *only* engages the third bone, the calcaneus bone, and describes the "majority of the shank" as "slid[ing] through" holes in the first two bones without stating that none of the threads engage a portion of, for example, the end of the second bone adjacent the third bone. *See id.* More importantly, even if this portion of Slater describes a *three*-bone embodiment where the threads only engage the third bone, Slater provides insufficient support for Petitioner's position that the threads of screw type 70 only engage the second bone in Slater's *two*-bone embodiment, which Petitioner relies on as the anticipatory embodiment of Slater. *See* Pet. 16; Ex. 1002 ¶¶ 114, 123–125 (arguing that Slater's Figure 1 shows two-bone embodiment). Slater contains no details on this aspect of its alternative two-bone embodiment, such that the threads of the screw may engage the end of the first bone adjacent the second bone and still provide satisfactory results. At best, Petitioner and Dr. Gall's related testimony establish that it would have been desirable, and perhaps obvious, to have the threads of screw type 70 only engage the second bone in Slater's two-bone embodiment to create a vise-like configuration that transfers

tensile load as claimed, but that does not establish that Slater expressly or inherently discloses such an embodiment to satisfy the anticipation standard.

We next address Petitioner's reliance on Slater's finite element analysis tests. *See* Reply 13–15. Petitioner did not rely on this aspect of Slater in the Petition, and raised the argument for the first time in Reply. *Compare* Pet. 26, *with* Reply 15; Sur-Reply 6–7. Setting aside the propriety of failing to rely on this aspect of Slater in the Petition, we are not persuaded by Petitioner's argument and evidence for two reasons. First, Petitioner appears to still rely on its argument that Slater discloses a "vise" configuration, and argues that the testing confirms the transfer of tensile load. *See* Reply 12–13 (relying on "vise" argument), 15 ("Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate."). Petitioner does not appear to argue that even if we find that Slater does not disclose the "vise" configuration and does not necessarily disclose screw threads that only engage the second bone, that the testing alone shows that Slater discloses the limitation. Reply 15. Accordingly, we do not find the testing argument persuasive due its link to arguments we find unpersuasive for the reasons discussed above.

Second, Patent Owner correctly points out that Slater provides inadequate information to conclude that the testing results apply to Slater's two-bone configuration such that we can conclude that Slater's two-bone embodiment results in the claimed transfer of tensile load to the plate's bridge. *See* PO Resp. 38–39 (citing Ex. 1002 ¶¶ 125, 160; Ex. 2002 ¶¶ 114–116; Ex. 2003, 92:24–93:7). Slater's tests merely simulate the response of its plate to certain loads, and do not purport to show actual loading of the plate on a patient in either the three-bone or two-bone embodiments.

Ex. 1005, 17:14–23 (referring to analysis of simulated in-vivo performance and "anticipated loadings" of the plate). Slater also emphasizes that the simulations only apply to "a plate of the particular type and geometry tested" and that "plates with different geometry and dimension . . . may result in different measured loadings and plate response" and "will be likely to have different load capacity results." *Id.* at 20:13–23. Based on the lack of detail as to how Slater's simulations would apply to its two-bone embodiment, and Slater's warning that the simulated results only apply to the specific plate tested, we agree with Patent Owner that Slater's simulated testing does not establish that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1 and 10.

Finally, for similar reasons, we find the testimony of Patent Owner's declarant Mr. Sommers more credible and persuasive than the testimony of Petitioner's declarant Dr. Gall. For example, Dr. Gall opines that Slater discloses a vise configuration, but fails to point to any portion of Slater disclosing that configuration with respect to the two-bone embodiment. *See* Ex. 1002 ¶ 125; Ex. 1027 ¶¶ 37–46. Again, this testimony may establish the desirability of such a configuration and that one of ordinary skill in the art, when using Slater's plate, may do so in the manner Dr. Gall proposes, but that does not establish that Slater expressly or inherently discloses a vise-like configuration due to threaded engagement with only the second bone in Slater's two-bone embodiment. We view the testimony of Mr. Sommers as more credible because it more accurately tracks Slater's disclosures. *See* Ex. 2002 ¶¶ 57–58 (opining that Slater "does not describe whether there would also be threads" in the second of the three bones in the three-bone embodiment, in practice the threads may engage multiple bones, and Slater

does not illustrate or describe how the screw would be used on a two-bone configuration), 81–83, 108–120 (opining that Slater fails to disclose the transfer of tensile load limitations).[2]

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1 and 10 and therefore does not prove, by a preponderance of the evidence, that Slater anticipates either of claim 1 or 11.

Petitioner's challenge to dependent claims 2–5, 9, 11, 12 and 13 as anticipated by Slater is substantially similar to its analysis of independent claims 1 and 10, which relies on Petitioner's predicate analysis on the independent claims. Pet. 27–32, 36. That analysis suffers from at least the same shortcomings discussed above for independent claims 1 and 10. Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5 and 9–13 are anticipated by Slater.

D. Ground 2: Obviousness of Claims 6 and 8 over Slater and Weaver

Petitioner contends that claims 6 and 8 are unpatentable for obviousness over Slater and Weaver. Pet. 36–39. Claims 6 and 8 depend from claim 1 and add, respectively, that transfixation screw hole or at least one attachment point includes features that lockably engage the transfixation

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[2] We are also unpersuaded by Petitioner's arguments based on the alleged similarity between the description Mr. Sommers provides of how the '776 patent shows the transfer of tensile load and Dr. Gall's description of how Slater transfers tensile load. *See* Reply 16–17. It is hardly surprising, and largely irrelevant, that Petitioner's declarant would describe the prior art in a manner consistent with the Patent Owner or its declarant's description of the how the challenged patent works. That similarity alone does not establish that the prior art expressly or inherently discloses the limitation in question.

screw head or locking bone screws. Ex. 1001, 12:52–554, 12:60–63. Petitioner alleges that those locking features are disclosed in Weaver and it would have been obvious to add them to Slater's plate to provide a more secure fixation between the screws and the plate. Pet. 36–39; Ex. 1002 ¶¶ 169–174. Petitioner otherwise relies on its anticipation analysis for claim 1 discussed above. Pet. 36–37.

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to Slater with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Slater and Weaver.

E. Ground 3: Anticipation of Claims 1–3, 6, and 8–12 by Falkner

Petitioner contends that Falkner discloses all elements of claims 1–3, 6, and 8–12, and thus anticipates those claims under 35 U.S.C. § 102(b). Pet. 39–57. To support its contention, Petitioner directs our attention to the foregoing discourses of Falkner and provides a detailed claim analysis addressing how each element of claims 1–3, 6, and 8–12 is disclosed by Falkner. Pet. 13–14, 39–57 (citing Ex. 1002 ¶¶ 175–230). Patent Owner raises multiple counterarguments. PO Resp. 43–53.

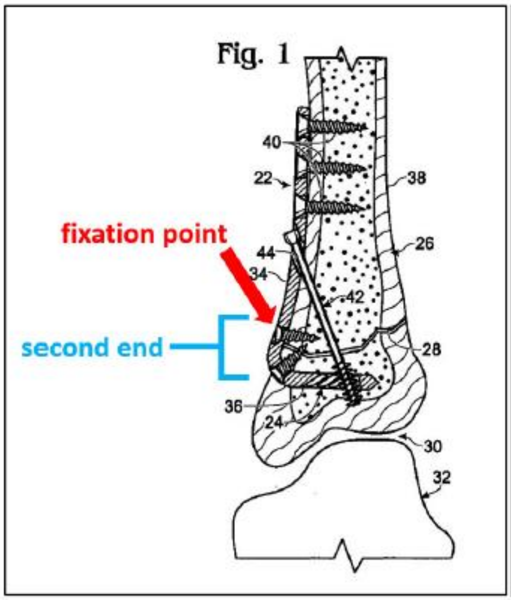
Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, and 8–12 are anticipated by Falkner. Our analysis follows.

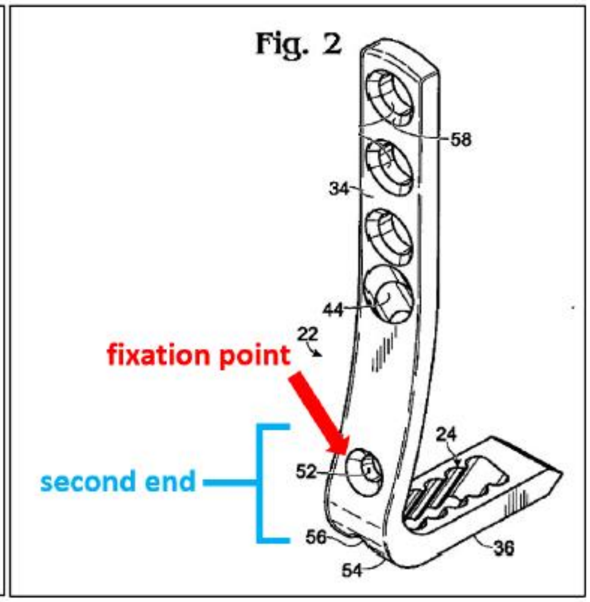
1. Petitioner's Contentions

We begin our analysis with Petitioner's contentions with regard to claim 1. Petitioner alleges that Falkner discloses claim 1's preamble. Pet. 40. According to Petitioner, although Falkner's Figure 1 shows a plating system for fixing a single bone having a fracture, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. *Id.* at 40 (citing Ex. 1006 ¶ 21). Petitioner also cites Falkner's disclosure that, in other examples, "***plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among them***." *Id.* (citing Ex. 1006 ¶¶ 27–29, 62).

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 41 (citing Ex. 1002 ¶ 175). And, Petitioner argues, "the inner surface [of the plate] would be configured to substantially conform with a geometry of the first discrete bone (tibia 26)." *Id.* at 42 (citing Ex. 1006 ¶ 23 and Ex. 1002 ¶ 180). According to Petitioner, this configuration would meet claim 1's "elongate spine" and "first end" limitations. *Id.* at 40–42.

For claim 1's "second end" limitations, Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.

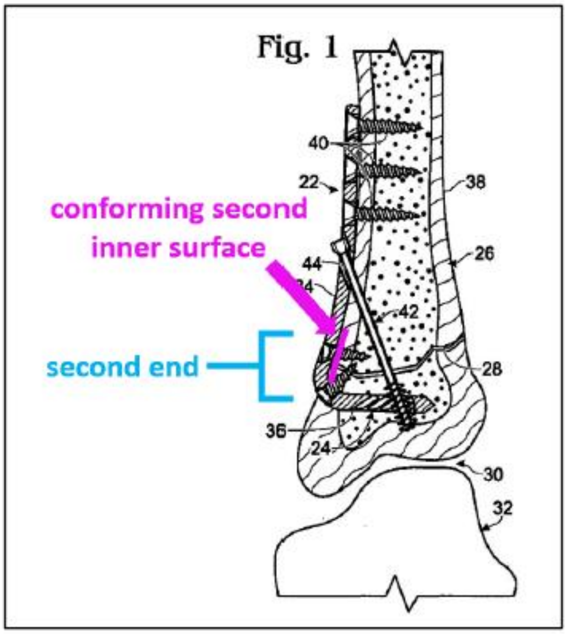




Pet. 43 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.*

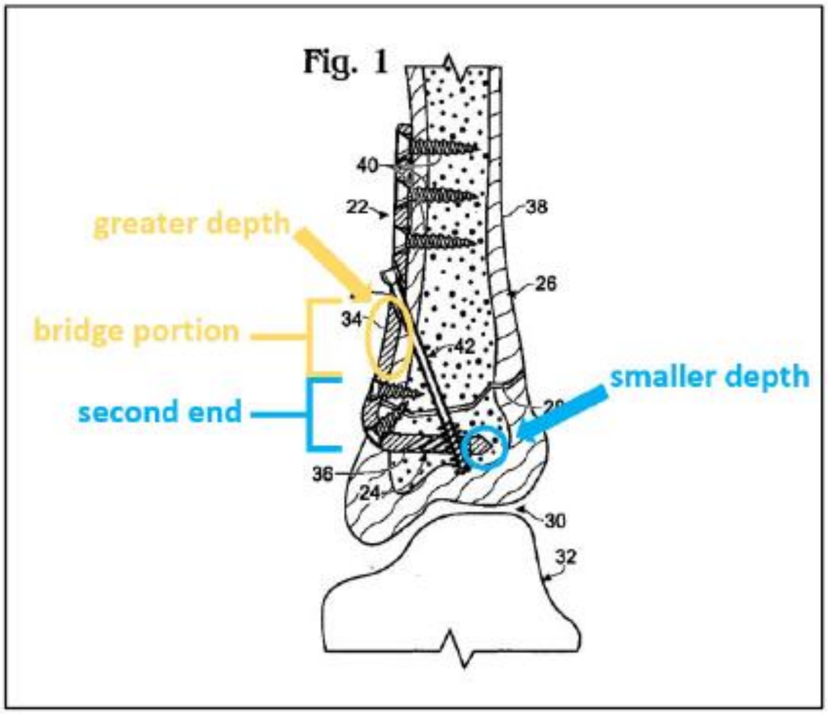
With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 43–44 (citing Ex. 1002 ¶ 181).

And, referencing another annotated version of Figure 1 (reproduced below), Petitioner contends that "the second inner surface would be configured to substantially conform with a geometry of the second discrete bone (talus 32)." *Id.* at 44 (citing Ex. 1002 ¶ 182).



Id. at 44; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner's plate attached to the tibia, including Petitioner's blue bracket designating the same alleged "second end," but here, Petitioner annotates (with purple arrow, line, and text) an alleged conforming "second inner surface." Pet. 44. Petitioner's position appears to be that this purple portion depicted in Figure 1 would be adapted and thus configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. *Id.*

Turning to claim 1's bridge portion and the requirement that the bridge portion have a depth or thickness greater than a portion of the first or second ends, Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 44–47. This annotated figure is reproduced below.



Id. at 46; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, above, shows the same plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval, bracketing, and text. Pet. 46. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" has a "greater depth." *Id.* This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as having a "smaller depth," which Petitioner highlights with a blue circle, arrow, and text. *Id.* From this, Petitioner argues that "at least a portion of the bridge portion has a thickness greater than at least a portion of the thickness of the second end." *Id.* (citing Ex. 1002 ¶ 185).

For the transfixation screw hole and transfixation screw limitations of claim 1, Petitioner cites Falkner's oblique opening (44) in external plate portion (34), and threaded fastener (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate's internal plate portion (36). Pet. 47–49. According to Petitioner, in a configuration where Falkner's plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* at 48. And, in that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred from the talus through the screw and into the bridge portion. *Id.* at 49 (citing Ex. 1002 ¶ 188). In support, Petitioner cites Falkner's teaching that "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." Pet. 49 (quoting Ex. 1006 ¶ 71).

2. Patent Owner's Response

Patent Owner makes three main arguments with regard to independent claims 1 and 10. PO Resp. 43–53. For purposes of this decision, especially given the parties' overlapping arguments, we focus on claim 1.

First, Patent Owner argues that Falkner fails to disclose a system for securing two discrete bones together across a joint between the two bones. *Id.* at 44–46. Patent Owner contends that Falkner's plate is not designed to secure the two discrete bones across a joint and further contends that "[t]o make a Falkner-type plate that crosses a joint would require extensive modification." PO Resp. 45–46.

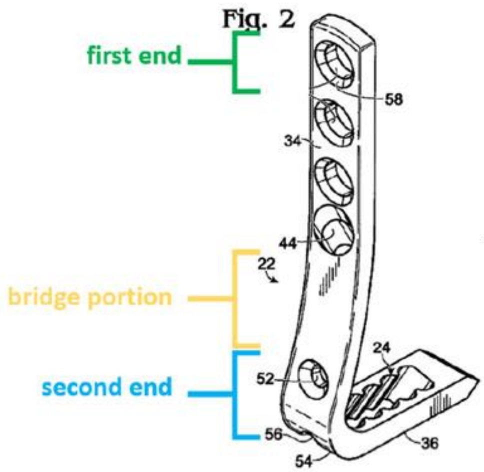
Second, Patent Owner argues that Falkner fails to disclose a "second end" that includes a "fixation point" and an "inner surface configured to substantially conform with a geometry of the second discrete bone" as required by the claims. *Id.* at 47–51. Patent Owner argues that what Petitioner identifies as the "second end" of Falkner's plate is inside the bone and therefore does not conform to the geometry of the second bone. *Id.* at 48. Patent Owner further contends that,

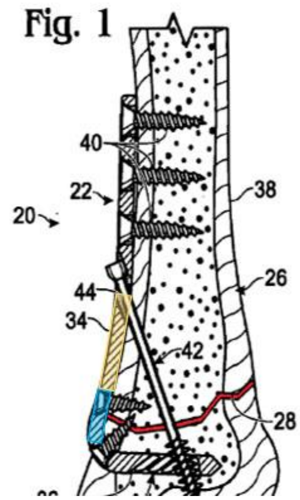
> With the interior portion of the Falkner blade-plate unable to conform to the geometry of the second discrete bone, the Petition relies on Dr. Gall, rather than the disclosure of Falkner, to conclude that "the plate 22 ***would have been*** placed across the joint 30 and the second inner surface ***would have been*** configured to substantially conform with a geometry of the second discrete bone (talus 32)." (Ex. 1002, ¶ 178 (emphasis added)). That something "would have been configured" is the hallmark of obviousness, and perhaps recognizing this after the fact, Dr. Gall at his deposition seemingly changed course and indicated that a Falkner plate spanning a joint would still include the portion that is interior to the bone. (Ex. 2003, 86:11–15). Therefore, Falkner fails to disclose a second end configured to "substantially conform with a geometry of the second discrete bone."

PO Resp. 48–49.

Third, Patent Owner contends that Petitioner's modified version of Falkner's plate does not have any portion configured to span across the bridge portion. *Id.* at 49–51. Patent Owner explains that even if the Falkner plate can be moved across the joint, the plate would cross the "second end", not the bridge portion. *See id.* at 51 ("the *Falkner* blade-plate 'bridge portion' that Petitioners rely upon would not cross the joint at all"). To illustrate that point, Patent Owner references and compares Dr. Gall's

annotated image of Falkner's figure 1, shown below on the left, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the right.





Id. at 55 (citing Ex. 1006 Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 183); Ex. 2002 ¶ 145 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as in would be applied to a bone. Ex. 1001 ¶ 8. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* at ¶¶ 9, 67. Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioners identify as the "second end." PO Resp. 52–53. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has identified, highlighted in blue, just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* (citing Ex. 2002 ¶ 146). Thus, according to Patent Owner, the Falkner plate does not cross the bone discontinuity in Figure 1.

3. Petitioner's Reply

In its Reply, Petitioner responds that "Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the [S]pecification 'may be positioned on and/or in any suitable bone(s) to span any natural or artificial discontinuity within a bone or between bones.'" Reply 17 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1028. Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes' testimony who believes that "Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***." Reply 18–19 (citing Ex. 1028, ¶¶ 19–20, 25–36). Instead, Petitioners cite to Dr. Holmes who describes a procedure whereby:

> surgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus" to help create a biomechanically stable joint for fusion. (Ex.1028, ¶¶31-32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Reply 19. Petitioner contends that Falkner "expressly enables a [person of ordinary skill in the art] to use its bone plate for joint fusion, and teaches all of the structural limitations set forth in the challenged claims." *Id.* at 20.

4. Patent Owner's Sur-Reply

In its Sur-Reply, Patent Owner responds that Falkner does not disclose the modifications required to anticipate the challenged claim and instead, the Petitioner relied heavily on Dr. Holmes' testimony on how the

plate could have been modified. Sur-Reply 17. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that the theory of anticipation raised in the Petition is obviousness in disguise." *Id.* at 18. Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-Reply 18–22 ("the extensive modifications required for Falkner's plate to be used across a joint go beyond what reasonably could be anticipation")

5. Analysis

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. Petitioner's position does not prevail for at least the reasons set forth on pages 44–53 of the Patent Owner Response and pages 18–22 of the Sur-Reply, which we adopt. In particular, we agree with Patent Owner that Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed. PO Resp. 44–45; Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured as claimed would apparently require at least some level of redesign or modification. Those might be simple, even arguably obvious, changes for the person of ordinary skill in the art in light of Falkner and its overall teachings, but Petitioner's challenge is based on anticipation. Indeed, Petitioner's and Dr. Gall's repeated invocation of how Falkner's plate, if

used in the hypothetical joint-spanning context, "would have been" configured rings of obviousness, not anticipation. *See, e.g.*, Ex. 1002 ¶¶ 180–184.

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But there is a dearth of detail about such a hypothetical plate's actual design. On this record, it appears to us that making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met (e.g., surfaces of the first and second ends that conform to a bone geometry, and a thicker bridge portion relative to the ends). The person of ordinary skill in the art might, for example, decide to conform some or multiple portions of the hypothetical bone plate to the exterior geometries of multiple bones, such as the tibia and talus. Such a design is even arguably suggested elsewhere in Falkner, where it discloses that bone plates "may be sized and shaped to conform to particular portions of a bone (or bones)" or "may be contoured generally to follow an exterior surface of a target bone (or bones)" (Ex. 1006 ¶¶ 33–34). But, here again, our concern is that such a theory drifts from anticipation—a doctrine still rooted in "strict identity"[3]—to obviousness.

Moreover, we note that Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate

[3] *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002).

that appears to be close to the middle of the plate and characterizes that portion as a "second end." Pet. 43. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id.* at 46. Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its anticipation position, while purporting to modify other portions of that embodiment (e.g., contouring the plate to a particular bony geometry) in order to render it suitable for a different attachment across multiple bones.[4] Such picking and choosing is indicative of obviousness.

Regarding independent claim 10, Petitioner acknowledges that many of the limitations recited in independent claims 1 and 10 are "nearly identical" with exceptions accounted for in its analysis set forth in the Petition. Pet. 54–56. Those differences between claim 1 and 10 identified by Petitioner do not cure the deficiencies discussed above with regard to claim 1. Thus, for at least the same reasons as discussed with respect to

[4] As a further example, Petitioner identifies opening (52) in Falkner's plate in Figure 1 as the alleged fixation point on a second end of the plate as claimed. Pet. 43. But, as described in Falkner, opening (52) and its corresponding bone screw is fixed on the *same side* of the bone discontinuity (fracture) as the plate portion Petitioner identifies as the plate's first end. Ex. 1006, Fig. 1. Inasmuch as a joint is simply another bone discontinuity in Falkner, Petitioner asserts, with minimal explanation, that a screw would have been placed through opening (52) to secure a second bone (e.g., talus) on the *opposite side* of the joint relative to the plate's first end when the plate is modified for use in this different context. *Id.* at 44; Ex. 1002 ¶ 184.

claim 1, we are not persuaded on the current record that Falkner anticipates claim 11.

Petitioner's challenge to dependent claims 2–3, 6, 8–10, 12–13, and 17 as anticipated by Falkner relies on Petitioner's predicate analysis on the independent claims. Pet. 49–54, 57. That analysis suffers from at least the same shortcomings discussed above for independent claims 1 and 10.

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–13, and 17 are anticipated by Falkner.

F. Ground 4: Obviousness of Claims 4, 5, and 13 over Falkner and Arnould

Petitioner argues that dependent claims 4, 5, and 13 would have been obvious over Falkner and Arnould. Pet. 57–60. Petitioner's argument under Ground 4 relies on Petitioner's predicate anticipation challenge under Ground 3 for those claims from which claims 4, 5, and 13 depend. *Id.* Petitioner relies on Arnould under Ground 4 only for allegedly teaching certain transfixation angles encompassed by claims 4, 5, and 13.

We determine that Ground 4 suffers from at least the same shortcomings as discussed above for Ground 3. Also, Petitioner contends a person of ordinary skill in the art would have been motivated to modify Falkner's bone plate to provide a plate specifically for use with a metatarsophalangeal joint and, in so doing, select the transfixation angles disclosed in Arnould. Pet. 57–60. Petitioner's anticipation analysis of Falkner, however, focused on the plate of Falkner's Figure 1, allegedly designed to render it suitable for use with the tibia and talus. Petitioner provides no sufficient explanation as to how this plate would be now designed and configured for an entirely different set of bones and joint—the

metatarsophalangeal joint—and still meet all the claim limitations of the underlying independent claims. *Id.* Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Falkner and Arnould.

G. Ground 5: Obviousness of Claims 1–5 and 9–13 over Arnould and Slater

Petitioner argues that claims 1–5 and 9–13 would have been obvious over Arnould and Slater. Pet. 60–76. To support its contention, Petitioner directs our attention to its detailed claim analysis addressing how each element of claims 1–5 and 9–13 is disclosed by Arnould and Slater. *Id.*; Ex. 1002 ¶¶ 244–300. Petitioner also contends that a person of ordinary skill in the art "would have been motivated to modify the bone plate of Arnauld with the thickened bridge portion of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." Pet. 65.

Patent Owner raises multiple counterarguments. PO Resp. 54–62. In particular, Patent Owner contends that thickening the portion of the Arnould plate Petitioner identifies as the bridge portion, "junction zone 14," would be contrary to the purpose of Arnould's disclosure. PO Resp. 55. Patent Owner further contends that Arnould in view of Slater fails to teach the elements of "a transfixation screw hole disposed along the spine." *Id.* at 57–59.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5 and 9–13 would have been obvious by the combination of Arnould and Slater. Our analysis follows. For independent claims 1 and 10, like Petitioner, our analysis focuses on claim 1. Pet. 60–68 (relying substantially on analysis of claim 1 for claim 10).

1. Independent Claim 1

a. Whether there is Motivation to Combine Arnould and Slater

Petitioner contends that "Arnould discloses each and every element of independent claim 1 except" the element "which recites 'at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end.'" Pet. 61 (citing Ex. 1002 ¶ 245). For that missing limitation, Petitioner turns to Slater, which Petitioner argues discloses a thicker bridge portion. *Id*. Petitioner argues that a person of ordinary skill in the art "would have been motivated to modify the bone plate of Arnould with the thickened bridge portion of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." *Id*. at 65 (citing Ex. 1002 ¶ 253); *see also* Reply 25 (there is motivation to combine Arnould and Slater "to strengthen the plate in the area that experiences the highest stress—the portion near the MTP joint.") (citing Ex. 1002 ¶¶ 253, 296; Ex.1027 ¶¶ 52–54).

Petitioner also explains that "[w]ith the use of a plate bender, a surgeon can adjust even a thickened portion of an MTP plate to conform to the variable anatomy of the metatarsophalangeal joint." Reply 25 (citing Ex. 1028 ¶ 34). Moreover, Petitioner contends that

> *Arnould* expressly contemplates a surgeon modifying the angle between the metatarsal and phalangeal parts of the bone plate to accommodate varying degrees of dorsiflexion. Bending the plate at the bend line weakens the plate, so thickening the plate at the bend line would improve the strength of the *Arnould* plate.

Id. (citing Ex. 1008 ¶¶ 20, 38; Ex. 1027 ¶ 56).

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that the proposed

motivation is contrary to the disclosure of Arnould for two reasons. PO Resp. 54–56. First, thickening the specified portion in Arnould "would be contrary to the purpose of Arnould's disclosure" because "it is designed in a specific manner to allow a surgeon to bend the plate at that junction zone to conform the plate in situ to a patient's bone anatomy." PO Resp. 55–56; Ex. 1008 ¶ 20; Ex. 2002 ¶¶ 155–157; *see also* Ex. 2002 ¶ 157 (Arnould's "junction zone 14" is "purposely not strengthened to allow for bending by the surgeon at time of implantation.") (citing Ex. 1008 ¶ 38).

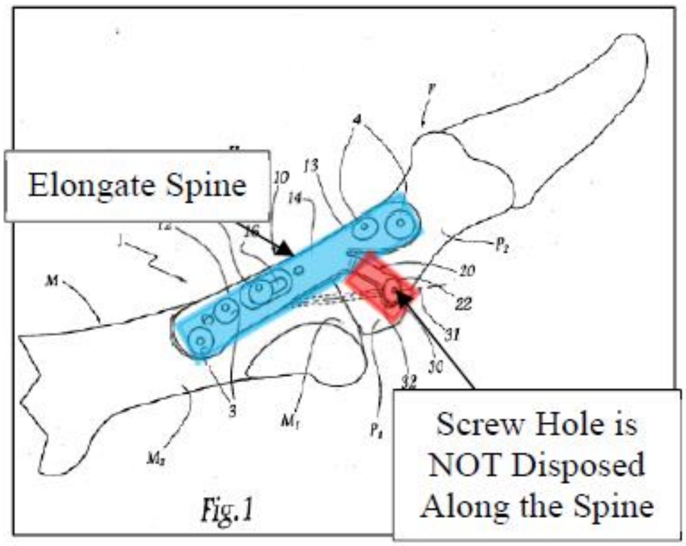
Second, there is no motivation to modify the plate in Arnould "[b]ecause the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest." PO Resp. 56–57. Rather, Arnould discloses that "the highest loading occurs in the cross-joint screw itself: 'this screw essentially, <u>**if not exclusively**</u>, takes up the bending stress generated during the patient's walking.'" PO Resp. 56 (quoting Ex. 1008 ¶ 6; citing Ex. 2002 ¶¶ 70, 165). "Because the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest, there would be no reason to modify that portion of the plate to accommodate additional stress as taught in Slater." *Id.* at 57.

b. Whether Arnould in view of Slater Fails to Teach a Transfixation Screw Hole Disposed Along the Spine

Claims 1 and 10 of the '776 patent specify that the "transfixation screw hole [is] disposed along the spine" of the plate. Ex. 1001, cl. 1, 10. The Petition relies solely on Arnould for this element. Pet. 67.

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that Arnould in view of Slater fails to teach or suggest a transfixation screw hole to be deposed along

the spine. PO Resp. 57–59. The alleged transfixation screw hole of Arnould is a "through-hole 25 (at the end of leg 20[)] . . . [and] is not disposed on the spine, but part of a separate leg piece that extends off the spine." *Id.* at 60. The following annotated version of Arnould's Figure 1 illustrates that point.



Id. at 57; Ex. 1008, Fig. 1. The annotated version of Arnould's Figure 1, above, shows plate (1) having a plate body (10) attached to the metatarso-phalangeal bones and joint, and Patent Owner has highlighted in blue the plate's longitudinal body, which Patent Owner calls the "Elongate Spine." PO Resp. 57. In red, Patent Owner highlights leg (20), which extends downward from the longitudinal side of the plate body near the plate's midsection. *Id.* Patent Owner also adds an arrow identifying a screw hole at the end of the leg (20), which Patent Owner adds "is NOT Disposed Along the Spine." *Id.*

Arnould discloses that leg (20) "is meant to wrap around the bone and is located vertically below the plate body," which is evident with reference to Figure 1 above. Ex. 1008 ¶ 23; Ex. 2002 ¶¶ 161, 172. Furthermore, as noted by Patent Owner:

> Arnould fails to disclose or suggest disposing screw 30 along the spine; and there is no reason in view of Arnould to locate a transfixation screw hole along the spine as required by the claims of the ’776 patent because the explicit advantage of Arnould is that the leg and screw were moved off the spine to generate “a significantly higher capacity to resist bending stresses than the plate body due to its structure and **implantation zone**.”

PO Resp. 58 (citing Ex. 1008 ¶ 6 (emphasis added); Ex. 2002 ¶ 165).

We have considered but are not persuaded by Petitioner’s Reply argument that

> Patent Owner incorrectly re-writes “disposed along the spine” as “disposed on the spine,” and improperly narrows the term “spine” to mean the center line of the plate. (POR, 60). The claim language nowhere equates the “elongate spine” with the center line of the plate.

Reply 26. Rather, we agree with Patent Owner that

> Something cannot be both along the body (or in the case of the claims, the spine) and below it. Petitioners also ignore the rest of claim 1, which requires that “the bridge portion [of the elongate spine] [be] configured to span across the joint,” and that “a transfixation screw hole [is] disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends through the bridge portion at a trajectory . . . [.]” (Ex. 1001, cl. 1). *Given that leg 20 is located below the body of the plate and does not cross the joint, it cannot be the claimed bridge portion*.

Sur-Reply 24 (emphasis removed; emphasis added).

c. Analysis of Remaining Claims

Petitioner’s analysis of independent claim 10 as obvious over Arnould and Slater is essentially the same as its analysis of claim 1. Pet. 74–75. That analysis suffers from at least the same shortcomings discussed above for claim 1. The same is true of Petitioner’s analysis of dependent claims 2–5,

9, 11, 12, and 13, which relies on Petitioner's predicate analysis on the independent claims. *Id.* at 69–73, 75–76.

2. Conclusion

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5 and 9–13 would have been obvious over Arnould and Slater.

H. Ground 6: Obviousness of Claims 6 and 8 over Arnould, Slater, and Weaver

Petitioner argues that claims 6 and 8 would have been obvious over Arnould and Slater, in further view of Weaver. Pet. 76–77. Petitioner's reliance on Weaver here is substantially the same as for Ground 2—citing Weaver's screw locking features and reasons to add them. *Id.* Claim 6 and 8 depend, however, from claim 1 and Petitioner's challenge under Ground 6 presumes Petitioner's predicate success on Ground 5. *Id.* (asserting that "independent claim 1 is rendered obvious by Arnould in view of Slater" before turning to claims 6 and 8).

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to the combination of Arnould and Slater with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Arnould, Slater, and Weaver.

III. CONCLUSION

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 9–13	102	Slater		1–5, 9–13
6, 8	103	Slater, Weaver		6, 8
1–3, 6, 8–12	102	Falkner		1–3, 6, 8–12
4, 5, 13	103	Falkner, Arnould		4, 5, 13
1–5, 9–13	103	Arnould, Slater		1–5, 9–13
6, 8	103	Arnould, Slater, Weaver		6, 8
Overall Outcome				1–6, 8–13

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6 and 8–13 of the ’776 patent are not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01451
Patent 9,351,776 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*, concurring.

I concur that Slater does not anticipate claims 1–5 and 9–13, and reach that result for the following additional reason.

Independent claim 1 recites a "transfixation screw hole comprising *an inner surface configured to direct the transfixation screw* through the transfixation screw hole *such that* the transfixation screw extends the bridge portion *at a trajectory configured* to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second

discrete bone once the plate is placed across the joint." Similarly, independent claim 10 recites a "transfixation screw hole comprising *an inner surface configured to direct a transfixation screw* through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion *at a trajectory configured* to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint." A dispute between the parties is whether the claim recitation for "an inner surface configured to direct the transfixation screw . . . at a trajectory" is taught by Slater.

To that point, Petitioner contends that Slater identifies openings 26 and 93 that "each receive a fixation screw that passes through those openings so that the screw is implanted at an angle." Pet. 24 (citing Ex. 1005, 11:19–21, 13:21–24, Figs. 1 and 7). More specifically, Petitioner contends that Slater's "transfixation screw hole (26 or 93) . . . comprises an inner surface (unnumbered in Slater's drawings) configured to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends through the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first discrete bone (tibia 4), a portion of the joint (2), and a second position on the second discrete bone (talus 3) once the plate (1 or 80) is placed across the joint." *Id.* at (citing Ex. 1002 ¶¶ 123–124; Ex. 1005, 11:19–25, 13:21–25).

In its Response, Patent Owner directs our attention to Figure 1 of Slater, and contends that this Figure "depicts, in phantom, the use of a screw that passes through the tibia and terminates in the talus." PO Resp. 10 (citing Ex. 2002 ¶ 55). "The hole that the screw 25 passes through is

constructed in a manner that allows the angle of the screw to be modified as the plate is affixed to the ankle joint." *Id.* at (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). "This hole is described as 'slotted,' meaning that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles." *Id.* at 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8); *see also* Ex. 1005, 16:28–30 ("One significant advantage of the plate described is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required."), Fig. 1.

Furthermore, Patent Owner notes that Slater "provides no detail regarding the structure of the inner surface of the hole" because a surgeon using Slater's plate "determines the path in situ with a range of options available." PO Resp. 33–34 (citing Ex. 1005, Fig 1; Ex. 2002 ¶ 97). That is, "Slater describes a plate that intentionally allows for varied angles through the same hole." *Id.* at 34–35 (citing Ex. 1005, 16:28–30 ("[o]ne significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required"); Ex. 2002 ¶ 103)). Patent Owner contends that, because the hole identified by Petitioner as Slater's transfixation screw hole allows for varied angles through the same hole, Slater fails to disclose a transfixation screw hole having "an inner surface configured to direct the transfixation screw through the transfixation screw hole . . . at a trajectory," where "trajectory" is properly interpreted to mean an "allowable fixed angle relative to the neutral bending axis of the joint." PO Resp. 17–20, 34–36.

In its Reply, Petitioner contends that Patent Owner's suggestion that trajectory limits the challenged claims to a single, fixed angle is

"unsupported by the intrinsic evidence." Reply, 4. Specifically, Petitioner contends that

> The claims recite only that the claimed "trajectory" is the transfixation screw trajectory, and that such trajectory is configured to pass through "a first position on the first [discrete] bone[, a portion of the joint,] and a second position on the second [discrete] bone" once the plate is placed across the joint. (EX1001, cls. 1, 11). *There is a wide range of angles at which this can be achieved, not just one fixed angle*. (EX1001, cl. 4; EX1027, ¶11)).

Reply, 2 (emphasis added). Petitioner further contends that "the inner surface of the transfixation screw hole does not, alone, determine the precise angle of the trajectory," as "the size, shape, and geometry of the screw also determine what angles the trajectory may have." *Id.* at 3 (citing Ex. 1027 ¶¶ 12–13).

Moreover, Petitioner contends that "Patent Owner's reliance on the 'neutral bending axis' as a point of reference for 'trajectory' is nonsensical" because "the neutral bending axis of a particular joint may shift depending on the position of the bone plate and the loads exerted on that joint" and, thus, "the 'trajectory' cannot be known by analyzing a bone plate or system alone." *Id.* (citing Ex. 2002 ¶ 39).

I begin this analysis by clarifying that I understand Patent Owner's position to be that the "inner surface of the transfixation screw hole" is not a hole configured to allow a screw to be inserted into a bone at a plurality of angles, but that the language of the claim requires a configuration that achieves a screw hole that directs a screw at a particular angle (or "trajectory"), where that angle may be configured within a certain range. PO Resp. 20 (citing Ex. 2002 ¶ 96; Ex. 1001, 6:25–30). Thus, the dispute between the parties is whether a singular "inner surface of the transfixation

screw hole" may be configured to operate so as to accommodate a range of angles, for example, in the same manner that Slater's oblique screw portal allows for screws to be inserted at varied angles through the same hole. *Id.*; Ex. 1002 ¶ 102 ("One significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required.") (quoting Ex. 1005, 16:28–30); Ex. 2002 ¶ 103 ("I agree with Dr. Gall that *Slater* teaches a screw hole that allows a screw to be inserted at a wide range of angles").

With that important distinction in mind, I consider Patent Owner's contention that the term "a trajectory" as used in the challenged claims means "an allowable fixed angle relative to the neutral bending axis of the joint." PO Resp. 18–20. Here, I note that the challenged claims themselves define what angles are "allowable." That is, an allowable angle for the transfixation screw is an angle that directs the screw "through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone." Ex. 1001, claim 1; *see also id.* at claim 10 ("through a first position on the first bone and a second position on the second bone").

Regarding Patent Owner's inclusion of the phrase "relative to the neutral bending axis of the joint" in its proposed construction of "trajectory," I recognize that the specification makes constant reference to the "neutral bending axis" and its relationship to the trajectory is defined by the disclosed transfixation screw hole. *See e.g.* Ex. 1001, 1:46–49 ("the trajectory may be configured to cross a neutral bending axis of the joint once the plate is placed across the joint"); *id.* at 2: 42–46 ("the inner surface of the transfixation screw hole in the plate may direct the transfixation screw along a trajectory that crosses a neutral bending axis of the joint"); *id.* at 5:53–57

("When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show in FIG. 2), a 'tension band' construct is created that puts transfixation screw 150 under tension when joint 106 flexes."). I also recognize Dr. Gall's and Mr. Sommer's statements explaining that the axis of a bone plate may generally approximate the direction of the neutral bending axis of the joint. Ex. 1002 ¶ 129; Ex. 2002 ¶ 94. Furthermore, later dependent claims, when accounting for the precise angles recited by those claims, expressly recite angles measured from the neutral bending axis of the joint. *See e.g.* Ex. 1001, claim 5 ("herein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis."). However, with regard to independent claims 1 and 10, I again find that the express recitation of "once the plate is placed across the joint" provides adequate basis for determining how a trajectory is defined, especially in view of the Dr. Gall's and Mr. Sommer's testimony, summarized above.[5] Ex. 1001, claims 1, 10; Ex. 1002 ¶ 129; Ex. 2002 ¶ 94.

The dispositive question is whether the recited transfixation screw hole is configured to direct the transfixation screw on a trajectory that is a fixed angle or is configured to allow for "adjustable orientation" based on "a predetermined allowable angular range" such as opening 26 of Slater,

[5] I also note that our express determination of whether a trajectory should be measured from an elongate axis, neutral bending axis of the joint, or otherwise, is unnecessary as such a determination would not affect the outcome of our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999)))

identified by Petitioner as the transfixation screw hole. Pet. 22; Ex. 1005, 12:23–25, 11:21–22. Here, I first note the specification does not describe a plate having a hole identified as a transfixation screw hole that would accommodate insertion of a screw at a plurality of angles through the same hole. Rather, the specification repeatedly describes the disclosed plate system as having a transfixation screw hole where it is the inner surface of that hole that is configured to direct a screw at a trajectory, which, according to Mr. Sommers, is language a person of ordinary skill in the art would understand to describe a degree of precision around a single fixed angle. Ex. 1001, 1:26–45, 2:8–14, 2:42–46; Ex. 2002 ¶¶ 50, 95, 97; PO Resp. 18–19. For example, the specification describes how "increased plate thickness around transfixation screw hole 102 may also enable transfixation screw hole 102 *to be machined* into bone plate 100 *at an angle* relative to the top surface of bone plate 100." Ex. 1001, 8:47–52 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:46–47; 6:19–33. By comparison, other holes in the disclosed plates are not disclosed with the same level of effort toward precision when describing the trajectory of a screw. Indeed, the specification even includes a description of an oblong opening such as the one found in Slater, described as compression hole 132 and serves the purpose of tightening bones so as to "to press together at the interface of joint 106." *Id.* at 8:53–9:26. Taken together, the specification, when read as a whole, describes plates with a transfixation screw hole configured at a single trajectory selected to achieve the functional objectives of the plate, namely, joint fusion, where that single trajectory is preferably between 30 and 70 degrees, and more preferably, 50 degrees. *Id.* at 6:19–33.

Petitioner's fails to direct us to any example or other disclosure to support its alternative interpretation, namely, a plate configured with a transfixation screw hole 102 configured to permit the placement of a screw at a plurality of trajectories or angles.

Second, other dependent claims support the interpretation of a trajectory configured at a fixed angle. Claim 2, for example, recites that the "central axis of the inner surface of the transfixation screw hole defines the trajectory," a distinguishing feature as compared to the device in Slater that I will discuss here by way of comparison. Ex. 1001, 12:32–36. Figure 1 of Slater depicts, in phantom, the use of screw 25 that passes through the tibia and terminates in the talus. PO Resp. 10 (citing Ex. 2002 ¶ 55). The hole that screw 25 passes through is oblique[6] and allows the angle of the screw to be modified as the plate is affixed to the ankle joint. *Id.* (citing Ex. 2002, ¶ 56; Ex. 1005, 11:21–22). In other words, the oblong hole of Slater is specifically designed to not have a central axis that defines the screw trajectory. (Ex. 2002, ¶ 124); *see also* Ex. 2002 ¶ 98 (Figure 1 of Slater "does not detail anything at all regarding the structure of [the 'inner surface' of the transfixation screw hole], much less demonstrate the hole has an

[6] It is undisputed that the hole identified by Petitioner as the transfixation screw hole is oblong. As noted by Patent Owner, this hole is described as "slotted," which means "that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles." PO Resp. 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8). Likewise, Dr. Gall recognizes the same hole as the transfixation screw hole of Slater and describes it as an "oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required." Ex. 1002 ¶ 114; Ex. 1005, 16:28–30.

'inner surface configured to direct the transfixation screw . . . at a trajectory.'")

Claim 4 includes an allowable range between 30 and 70 degrees for the trajectory. Claim 4, however, depends from claim 2, and therefore requires the central axis of the screw hole to define the trajectory of the screw between 30 and 70 degrees. Upon review of this claim structure for the '776 patent, I agree with Patent Owner that a person of ordinary skill in the art would understand that, in the context of the intrinsic record, this means that any given plate is configured at a single trajectory or single fixed angle, and that different plates could have a different fixed angle, with plates having single fixed angles in the range between 30 and 70 degrees. PO Resp. 20 (Ex. 2002 ¶ 96; *see also* Ex. 1001, 6:25–30). Here, I also credit Mr. Sommer's explanation that a person of ordinary skill in the art would understand that to mean that a surgeon would be provided with a kit that includes multiple plates, each one with a single fixed angle of, for example, 50, 55, 60, 65 and 70 degrees. Ex. 2002 ¶ 96; Sur-Reply, 4. Moreover, claim 5 further limits the trajectory of claim 4 to "a transfixation angle of about 50 degrees measured from the neutral bending axis." Ex. 1001, cl. 5. Claim 6 further limits claim 1 and requires that "the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw," and that engagement of the screw head and screw hole would inherently constrain the configuration of the screw hole to a particular angle. Thus, each of dependent claims 2–6 further limit claim 1 along the lines of a single "trajectory" and are more specifically directed to plates configured with a screw hole that defines a single trajectory.

Finally, while the term "trajectory" used in isolation may not necessarily connote a fixed angle, the assessment here is whether the recitation of an inner surface of a screw configured to direct a screw *at a trajectory* is describing a fixed angle, and more specifically, describing a screw hole configured to direct a screw at a single trajectory. In view of the claim structure of independent claims 1 and 10, the content of the specification, and testimony of Mr. Sommer's, summarized above, I determine it does. The claims expressly require a transfixation screw hole that itself is "configured to direct the transfixation screw through the transfixation screw hole . . . *at a trajectory*," which in context indicates that a screw hole directs the trajectory of the screw, even if other factors may also influence the trajectory. *Cf*. Reply 3–4. In other words, we agree with Patent Owner that "[a person of ordinary skill in the art] reading [claims 1 and 10] in light of the intrinsic record would understand that [the claim language describing the recited screw hole] means that the shape of the inner surface of the transfixation screw hole is such that it guides the screw at a fixed angle." PO Resp. 19; Ex. 2002 ¶ 95.

I recognize Petitioner's argument that "[w]hile Slater's transfixation screw hole allows the transfixation screw to be positioned within a predetermined range, once the screw is threaded into the bone, the screw trajectory, and thus the angle, is fixed," however, I am not persuaded. Reply 12. Petitioner insufficiently explains how the fixation of the angle of the screw trajectory by virtue of being inserted into a bone equates to the claim requirement that the inner surface of the transfixation screw hole directs the screw at a trajectory.

Petitioner's challenge to dependent claims 2–5, 9, 11, 12, and 13 as anticipated by Slater is substantially similar to its analysis of independent claims 1 and 10, which relies on Petitioner's predicate analysis on the independent claims. Pet. 26–32, 36. That analysis suffers from at least the same shortcomings discussed here for independent claims 1 and 10.

In view of the above, I determine that Slater does not disclose "the transfixation screw hole comprising an inner surface configured to direct the transfixation screw . . . at a trajectory." Slater's opening 26 is meant to be a variable angle hole and not an opening configured to direct a screw at a particular angle or trajectory. *See* Ex. 1005, 11:19–22 ("an angle within a predetermined allowable angular range"); *see also* Ex. 2003, 65:1–4 (Dr. Gall agreeing that each of the angles depicted by phantom screws shown in Figure 1 of Slater are achieved through the same screw hole 26). Accordingly, for this additional reason, I determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5 and 9–13 are anticipated by Slater.

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Paper 46
Date: March 14, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01452
Patent 9,763,716 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges.*

Opinion by the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* SNEDDEN.

DECISION
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") and OsteoMed LLC ("Patent Owner"). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–6, 8–13, and 16–19 ("Challenged Claims") of U.S. Patent No. 9,763,716 B2 ("the '716 patent," Ex. 1001) are unpatentable.

A. Background and Summary

Petitioner filed a Petition to institute *inter partes* review of claims 1–6, 8–13, and 16–19 of the '716 patent. Paper 2 ("Pet." or "Petition"). Patent Owner filed a Preliminary Response. Paper 5.

Following institution, Patent Owner filed a Response to the Petition (Paper 23, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 27, "Reply"), and Patent Owner filed a Sur-Reply (Paper 33, "Sur-Reply").

On December 15, 2023, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 42.

B. Related Matters

The Petition identifies three other patents as related to the '716 patent. Pet. 2. Those patents are: U.S. Patent No. 8,529,608 ("the '608 patent); U.S. Patent No. 9,351,776 ("the '776 patent"); and U.S. Patent No. 10,245,085 ("the '085 patent"). *Id.* The '608 and '776 patents issued on grandparent

and parent applications, respectively, to the ’716 patent, and the ’085 patent issued on a child application to the ’716 patent. Ex. 1001, code (63); IPR2021-01453 (Exhibit 1001, code (63)).

The four related patents are asserted in two pending lawsuits. Pet. 1–2; Paper 3, 1. Those lawsuits are: *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.); and *OsteoMed LLC v. Wright Medical Technology, Inc.*, Case No. 1:20-cv-01621 (D. Del.). *Id.*

In addition to this IPR proceeding, other claims of the ’716 patent and the related patents are challenged in other matters before the Board. Those matters include: IPR2021-01450 and IPR2022-00189 (challenging claims of the ’608 patent); IPR2021-01451 and IPR2022-00190 (challenging claims of the ’776 patent); IPR2021-01453 (challenging claims of the ’085 patent); and IPR2022-00191 (challenging claims of the ’716 patent). Pet. 2.

C. The ’716 Patent

The ’716 patent issued September 19, 2017, from an application filed May 5, 2016. Ex. 1001, codes (45), (22). The ’716 patent claims the priority benefit of an application filed April 28, 2009. *Id.* at 1:7–13.

As background, the ’716 patent explains, when reconstructing a damaged joint, “a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint,” and “[o]ne way to achieve this objective is to attach the bones of the joint to a plate that holds the bones together in alignment with one another while they fuse together.” *Id.* at 1:24–31.

The ’716 patent relates to “a device for securing bones together, and more particularly, to a bone plate with a transfixation screw hole.” *Id.* at 1:18–20. The ’716 patent describes a plate that includes, *inter alia*, an

elongate spine with first and second ends having attachment points for securing the plate to first and second bones on, respectively, first and second sides of a joint between the bones. *Id.* at 1:39–45. The plate's spine also includes a "bridge portion" configured to span the joint, and a "transfixation screw hole disposed along the spine." *Id.* at 1:45–49. The transfixation screw hole may be configured to direct a transfixation screw such that the screw extends alongside the bridge at a trajectory that passes through a first position on a first bone and a second position on a second bone when the plate is placed across a joint. *Id.* at 1:49–55.

Figures 1 and 2 of the '716 patent, reproduced below, illustrate various features of an exemplary bone plate, and the plate's placement across a joint. Figure 1 shows a failed joint in a human foot, and Figure 2 shows a bone plate being used to repair the aforementioned joint.

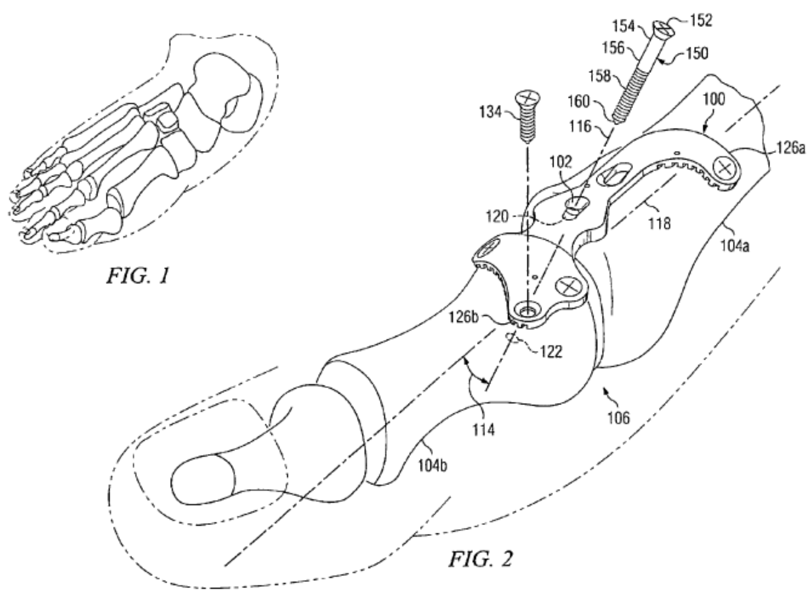

FIG. 1

FIG. 2

Id. at Figs. 1–2. Figure 1 is a perspective view of a human foot and illustrates the bones within the foot, including a failed metatarso-phalangeal

joint of the big toe. *Id.* Figure 2 depicts a bone plate (100) being used in combination with a transfixation screw (150) to repair the joint (106) between a first bone (104a) and a second bone (104b) when the transfixation screw is screwed through the joint along a trajectory defined by the central axis (116) of transfixation screw hole (102) that crosses neutral bending axis (118) of the joint. *Id.* at 4:25–43, 6:7–11, 6:62–67.

Figure 3, reproduced below, is an enlarged isometric view of the top surface of the plate of Figure 2.

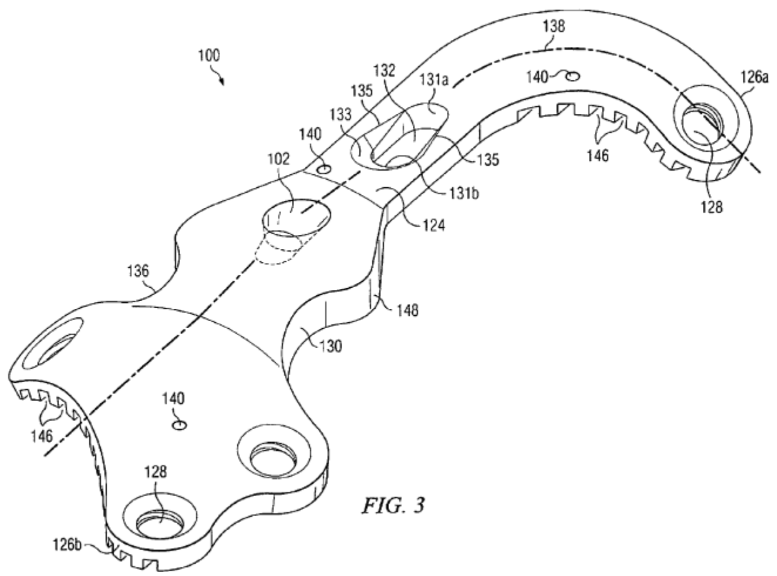

FIG. 3

Id. at Fig. 3. Figure 3 shows plate (100) and various features, including elongate spine (124) having a first end (126a) and a second end (126b), each end with attachment points (128). *Id.* at 7:41–49. The attachment points (128) may be made to accept a bone screw (134, as depicted in Fig. 2) for attaching the first and second ends to first and second bones. *Id.* at 7:53–61. The plate includes bridge portion (130) configured to span a joint between the bones, which bridge portion includes a "thickened section 136 . . . to increase the bending strength" and minimize bending or breaking when load is applied to the joint. *Id.* at 7:48–50, 8:32–36. The plate further includes a

transfixation screw hole (102) "disposed along the center line 138 of spine 124, immediately adjacent to bridge portion 130." *Id.* at 8:53–58.

According to the '716 patent, the inner surface of the transfixation screw hole may direct a transfixation screw along a path that passes through a portion of first and second bones and crosses a neutral bending axis of the joint. *Id.* at 2:59–63. The patent explains that "[t]his technical advantage may create a 'tension band' construct that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint." *Id.* at 2:63–67; *see also id.* at 6:7–11 ("When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show[n] in FIG.2), a 'tension band' construct is created that puts transfixation screw 150 under tension when joint 106 flexes.").

D. Illustrative Claims

The '716 patent includes three independent claims (claims 1, 10, and 16), all of which are challenged here. Claim 1 is illustrative and reads:

> 1. A system for securing two discrete bones together across a joint between the two bones, comprising:
>
> an elongate spine having:
>
> a first end comprising:
>
> at least one fixation point for attaching the first end to a first discrete bone on a first side of an intermediate joint; and
>
> a first inner surface configured to substantially conform with a geometry of the first discrete bone;
>
> a second end comprising:
>
> at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and

> a second inner surface configured to substantially conform with a geometry of the second discrete bone; and
>
> a bridge portion disposed between the first end and the second end, at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end; and
>
> a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends the bridge portion[1] at a trajectory configured to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone; and
>
> a transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion.

Ex. 1001, 12:24–64.

As recited above, claim 1 is to a "system." Claims 10 and 16 are directed to a "plate" for securing two discrete bones across a joint, but otherwise include many limitations similar to claim 1 (e.g., an elongate

[1] The phrase "extends the bridge" appears to be missing language. We note that a claim correction was made for the related '608 patent, changing the phrase "extends the bridge" to "extends through the bridge." IPR2021-01450 (Ex. 1001, 14 (Certificate of Correction)). Claims 10 and 16 of the '716 patent, in contrast, include the phrase "extends alongside the bridge." Ex. 1001, 13:54, 14:40. Beyond claim 1, we find no instance of the phrase "extends the bridge" in the '716 patent. For purposes of this Decision, we will interpret "extends the bridge" as encompassing both "extends through the bridge" and "extends alongside the bridge."

spine, first and second ends with fixation points and that the ends conform with a geometry of the first and second bones, respectively, and a transfixation screw hole disposed along the spine). Ex. 1001, 13:34–61, 14:19–48. Unlike the "system" of claim 1, claims 10 and 16 do not require a "transfixation screw" as an affirmative claim limitation—the term appears in a functional sense in further describing the configuration of the recited "transfixation screw hole." *Id.* Claims 10 and 16 also include "wherein" clauses that specify that "at least a portion of said bridge portion and said transfixation screw hole has a [depth] [or "thickness," for claim 16] greater than at least a portion of said first and second ends." *Id.*

E. Prosecution History

Starting with the '608 patent's prosecution history, the Examiner initially rejected "system" and "plate" claims similar to claims appearing in the '716 patent for anticipation by Grady (Ex. 1011) and for obviousness based on Grady in view of Strnad (Ex. 1015). Ex. 1004, 173–178.[2] At that time, the Examiner apparently interpreted a "joint" as recited in the claims as including a "fracture" within a single bone, and also found that Grady's system was "capable of securing two bone portions together" across a joint. *Id.* at 175. Applicant responded by arguing, *inter alia*, that Grady's bone plate was dimensioned and configured for "fixation of ***two portions of a single bone***, which has been fractured," and did not teach a transfixation screw hole configured to direct the screw so that it "extends ***at a trajectory configured to pass through two bones*** once the plate is placed across the joint" as claimed. *Id.* at 498.

[2] These page numbers refer to the page numbers added to the exhibit copy, not the original pagination, nor the Bates numbering on the exhibit.

The Examiner responded by maintaining the rejections, characterizing Applicant's arguments as based on an "intended use" of the claimed subject matter without a showing of a "structural difference" between the claims and the prior art. *Id.* at 227–234 (reiterating that Grady's plate is "capable of" performing the intended use).

Through additional back-and-forth between the Applicant and the Examiner, including multiple claim amendments, the claims were ultimately allowed. The claims were initially amended to require first and second inner surfaces of the system/plate conform with a geometry of a first and second bone. *Id.* at 246, 249. The Examiner, however, determined that such amendment did not go far enough in distinguishing the claims *structurally* over Grady. *Id.* at 267–268 (explaining that "if the applicant were to add language to recite the **structural differences** between the claimed invention and the prior art, it would overcome the rejection of record."). Applicant then amended the claims further to recite: (i) that first and second bones to which the plate/system are attached are "discrete" bones and the joint was an "intermediate" joint between them; (ii) that the bridge portion included a "thickness greater" than a portion of the first or second ends; and (iii) that the transfixation screw and screw hole are configured in such a way as to transfer tensile load from the second discrete bone through the screw and into the bridge portion. *Id.* at 289–291, 296–297 (arguing these amended features are not disclosed in Grady or Strnad). The Examiner subsequently allowed the claims without substantive comment. *Id.* at 305–309.

Prosecution of the related '776 and '716 patents included non-statutory double patenting rejections (overcome via terminal disclaimer), but no prior art rejections before allowance. *See generally* Exs. 1017 and 1018.

The prosecution of the ’716 patent also included rejections for indefiniteness and written description that were overcome by minor claim amendment and cancellation of certain claims. Ex. 1017, 179, 197–198, 207.

F. Asserted Grounds

Petitioner asserts that claims 1–6, 8–13, and 16–19 are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1–5, 9–13, 16–19	102(b)[3]	Slater[4]
6, 8	103(a)	Slater, Weaver[5]
1–3, 6, 8–12, 16–18	102(b)	Falkner[6]
4, 5, 13, 19	103(a)	Falkner, Arnauld[7]
1–5, 9–13, 16–19	103(a)	Arnauld, Slater
6, 8	103(a)	Arnauld, Slater, Weaver

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1027) and Dr. George B. Holmes, Jr. (Ex. 1028) to support its contentions.

Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

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[3] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Based on the putative effective filing date of the ’716 patent, we apply the pre-AIA versions of §§ 102 and 103.

[4] Slater, WO 2007/131287 A1, published Nov. 22, 2007 (Ex. 1005, “Slater”).

[5] Weaver et al., US 6,623,486 B1, issued Sept. 23, 2003 (Ex. 1009, “Weaver”).

[6] Falkner, US 2005/0171544 A1, published Aug. 4, 2005 (Ex. 1006, “Falkner”).

[7] Arnauld, EP 1 897 509 B1, published Mar. 12, 2008 (Ex. 1007). Petitioner states that Exhibit 1008 is a certified English translation of Exhibit 1007 (Pet. 4) and, for purposes of this Decision, we refer to Exhibit 1008 as “Arnauld.”

G. Level of Ordinary Skill in the Art

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

Petitioner proposes that a person of ordinary skill in the art ("POSA" or "POSITA") at the time of the invention

> would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon.

Pet. 9 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner's proposal about the POSA's qualifications. PO Resp. 24.

For this Decision, we adopt and apply Petitioner's proposal for the POSA level, which does not appear to be inconsistent with the level of skill reflected in the asserted prior art.

H. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner takes the position that "[t]here are no claim terms in the Challenged Claims that require construction" and that Petitioner has "applied the ordinary and customary meaning of each claim term." Pet. 9–10 (*citing Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)).

Patent Owner contends that the term "trajectory" as used in the Challenged Claims "means a fixed angle relative to the neutral bending axis of the joint." PO Resp. 18.

Having considered the parties' positions and evidence of record, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

II. ANALYSIS

A. Introduction

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring inter partes review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in inter partes review).

"Anticipation is a question of fact, as is the question of what a [prior art] reference teaches." *In re NTP, Inc.*, 654 F.3d 1279, 1297 (Fed. Cir.

2011). "Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). Whether a reference anticipates a claim is assessed from the skilled artisan's perspective. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003) ("[T]he dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching that every claim element was disclosed in that single reference." (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991))).

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness.[8] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

The obviousness inquiry also typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). A petitioner cannot prove

[8] Patent Owner does not present any objective evidence of nonobviousness (i.e., secondary considerations) for the challenged claims.

obviousness with "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Rather, a petitioner must articulate a sufficient reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016).

We analyze the asserted grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of success at trial.

B. Overview of the Asserted Prior Art

1. Slater (Ex. 1005)

Slater is an international patent application published on November 22, 2007. Ex. 1005, code (43). Slater relates to "prosthetic devices and more particularly relates to an ankle fusion plate for fusion of the anterior ankle." *Id.* at 2:6–7.[9] Although Slater's plate is "described with reference to its application to ankle fusion," Slater discloses that "it will be appreciated by persons skilled in the art that the invention may be applied to the repair/fusion of other bones requiring axial alignment." *Id.* at 7:34–8:2.

Figure 1 of Slater, reproduced below, shows a side elevation of an example plate attached via fixation screws to an abbreviated ankle joint.

[9] These page number citations in Slater are to the page numbers added to the exhibit copy, and the applicable line numbers on those pages. For other asserted prior art, however, we may cite to the numbered paragraphs within the reference, or to the column and line numbers.

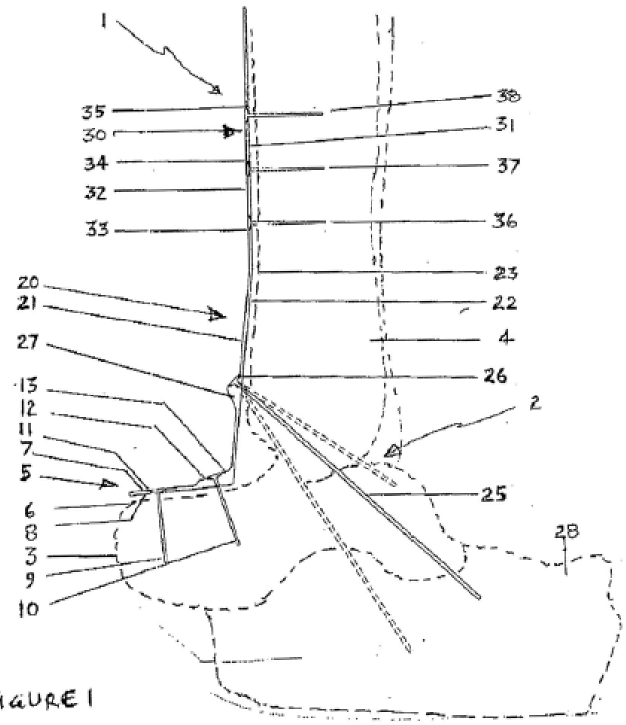


FIGURE 1

Id. at Fig. 1. Slater's Figure 1, above, shows plate (1) attached to an ankle joint (2) opposing the talus bone (3) and the tibial bone (4). *Id.* at 12:2–4. Figure 1 depicts plate (1) having inner (22) and outer (21) surfaces, with inner surface (22) opposing the anterior surface (23) of the tibia (4). *Id.* at 12:18–19. Portion (30) of the plate includes openings (33, 34, 35) for receiving fastening screws (36, 37, 38), which engage tibia (4). *Id.* at 12:28–31. Portion (5) of the plate has inner (8) and outer (7) surfaces that oppose surface (6) of the talus bone (3) for fixation thereto by screws (9, 10), which pass through openings (11, 12) and into the talus. *Id.* at 12:5–10.

In addition, portion (20) of Figure 1's plate resides between portions (5) and (30), and includes opening (26) in formation (27), for receiving fixation screw (25). *Id.* at 12:18–22. According to Slater, "[f]ormation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range . . . preferably within a 40 degree arc." *Id.* at

12:21–23; *see also id.* at Fig. 2 (front elevation view of plate 1, showing another view of plate portions (20, 30), openings (33, 34, 35) and formation (27) relative to the underlying anterior tibia (4) and talus (3) to which the plate is attached).

Slater discloses that "[s]crew 25 engages tibia 4, talus 3, and calcaneus 28 [(i.e., heal bone)] effectively providing three points of fixation according to this embodiment." *Id.* at 12:23–25. Continuing, Slater teaches that, "[a]s may be seen in figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis," and "[t]his is also necessary to achieve maximal compression of the fusion site/s." *Id.* at 13:3–5.

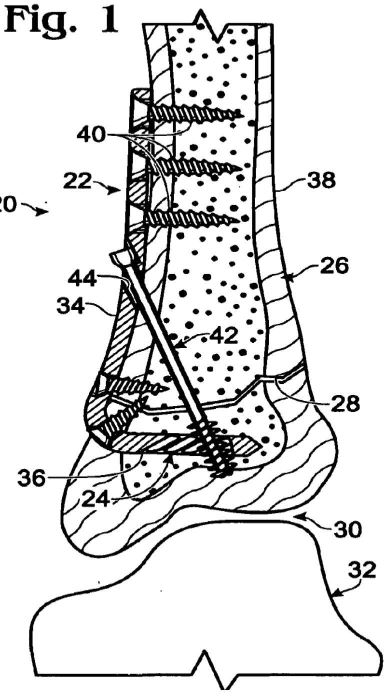
In summarizing features of its invention, Slater discloses that the plate's depth may change at different locations and "[p]referably, the depth at the beginning arid [*sic*, and] end points of the L shaped contour over the ankle joint[ ] will be at it's maximum thickness." *Id.* at 9:31–34; *see also id.* at 10:3–6 ("The plate will taper at at least one but preferably two different points of the plate . . . [and] [t]he desired effect is for the plate to taper in and decrease in thickness proximally."). Slater further teaches that the plate "will preferably resemble and conform to the typical geometry of the anatomical region. . . . Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint." *Id.* at 10:11–15.

2. Falkner (Ex. 1006)

Falkner is a U.S. patent application that published August 4, 2005. Ex. 1006, code (43). Falkner relates to systems for fixing bones using bone plates having toothed apertures for retaining fasteners. *Id.* ¶ 7.

Falkner's Figure 1, reproduced below, is a cross-sectional view of an example bone plate including a toothed aperture with the plate secured to a fractured bone. *Id.* ¶ 8.

Fig. 1



Id. at Fig. 1. Falkner's Figure 1 shows bone plate (22) with toothed aperture (24) attached to the tibia (26) and spanning fracture (28). *Id.* ¶ 21. As illustrated, external plate portion (34) is secured to the tibia with a suitable fastener, such as bone screw (40), and internal plate portion (36) is disposed substantially interior to the tibia. *Id.* ¶¶ 23–24. The internal plate portion (36) defines a toothed aperture (24) configured to receive threaded fastener or screw (42) inserted through opening (44). *Id.* ¶ 24. According to Falkner, "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region . . . into/through the aperture applies a tension to the plate." *Id.* ¶ 71; *see also id.* at Fig. 2 (showing a more detailed view of toothed aperture (24)).

Although the above embodiment is shown attached to a single bone and spanning a fracture in that bone, Falkner discloses that a plate may be used to span other bone discontinuities—including discontinuities between more than one bone. *Id.* ¶¶ 27–28 (disclosing that discontinuities include fractures (breaks in bones) and joints). Falkner discloses that "[i]n other examples, plate 22 may span a joint, such as a joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21.

Falkner teaches that the inner and outer surfaces of a bone plate "may be generally complementary in contour to the bone surface." *Id.* ¶ 34. Moreover, Falkner discloses, "[t]he thickness of the plates may vary between plates and/or within plates, according to the intended use." *Id.* ¶ 35.

3. Arnauld (Ex. 1008)

Arnauld is a European patent application that published March 12, 2008. Ex. 1008, code (43). Arnauld "relates to an arthrodesis [(i.e., fusion)] plate for a metatarso-phalangeal joint, particularly for the joint between the first metatarsal and the first phalanx of the big toe." *Id.* ¶ 1.

Arnauld describes a disadvantage with conventional plates "in the form of an elongated, generally flat body placed against the upper surfaces of the metatarsal and phalanx straddling the joint to be locked." *Id.* ¶ 2. More specifically, Arnauld discloses that, "when the patient walks, his metatarsal-phalangeal joints are subjected to a flexion movement linked to the progressive support of his plantar arch, from the heel to the toes," however, "[f]or the joint locked by the [conventional] plate, the bending stress is essentially absorbed by this plate which, through a cyclical repetition of this stress, weakens the bone anchorage of the screws holding the plate against the fused bones." *Id.* ¶ 3.

Arnauld aims to remedy that disadvantage, describing a plate designed for durable fixation and that includes a "leg" structure extending laterally from the plate that "allows the plate to be attached to a lateral surface of the epiphysis of the phalanx—that is to say, in anatomical terms, to the medial surface of the phalangeal base." *Id.* ¶¶ 5–6. According to Arnauld,

> this leg is shaped so that its end hole can receive a long screw … which will extend both through the bone material of the phalanx and into the bone material of the metatarsal . . . so that this screw essentially, if not exclusively, takes up the bending stresses generated during a patient's walking, it being noted that, due to its position, the screw works mainly by means of a traction.

Id. ¶ 6 ("Since this screw has a significantly higher capacity to resist bending stresses than the plate body due to its structure and implantation zone, the implantation of the plate is stable over time.").

Arnauld's Figure 1, reproduced below, shows an arthrodesis plate fixed to the metatarso-phalangeal joint.

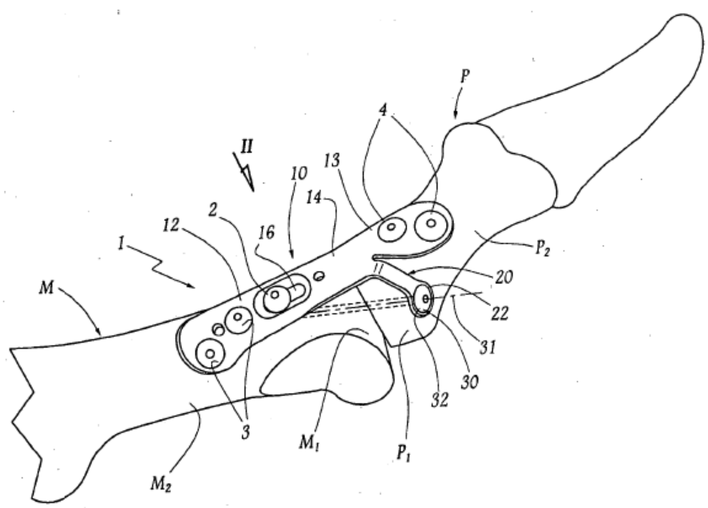


Fig. 1

Id. at Fig. 1. Figure 1 of Arnauld, above, shows plate (1), having a plate body (10) that includes, in the longitudinal direction, a metatarsal portion (12) and a phalangeal portion (13) that are adapted to be fixed to the

underlying metatarsal (M) and phalanx (P) bones, and joint portion (14) between the metatarsal and phalangeal portions that is configured to overlie the joint zone. *Id.* ¶ 14; *see also id.* ¶ 21, Fig. 2 (vertical view of the plate itself without bones, and showing through-holes (e.g., 12_1 and 13_1) in the respective portions for receiving bone-anchoring screws).

Figure 1 of Arnauld also shows leg (20) located on the inner longitudinal side and extending from the plate body. *Id.* ¶ 23. As Arnauld explains, "leg 20 thus gives the impression of plunging downward in relation to the plate body 10, so that its end . . . is located vertically below this plate body in the configuration of implantation of the plate 1." *Id.* Further, "the leg 20 is bent downward relative to the plate body along a bend line 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the leg and the phalangeal portion 13." *Id.* ¶ 24; *see id.* at Fig. 2 (depicting bend line (23) and longitudinal direction (21)).

Arnauld teaches that, at the end (22) of leg (20) is a through-hole (25) adapted to receive a screw (30). *Id.* at Figs. 1, 2; *see also id.* ¶ 26. According to Arnauld, "[t]his screw 30 is a long screw in that sense that, as shown by the dotted line in Figure 1, it has sufficient length to extend from the hole 25 into both the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, and possibly also into the metatarsal diaphysis M_2." *Id.* ¶ 26.

4. Weaver (Ex. 1009)

Weaver is a U.S. patent that issued September 23, 2003. Ex. 1009, code (45). Weaver relates to bone plating systems. *Id.* at Abstr. Weaver describes, among other things, locking screws that include threading on the outer surface of the head of such screws, which threading mates with corresponding threading on the surface of a hole on the plate for receiving

such screws. *Id.* at 1:49–54. Weaver teaches that such locking screws and corresponding features on the plate for receiving the screws may provide improved resistance to shear and torsional forces and reduce screw loosening. *Id.* at 1:46–48, 1:57–58, Figs. 2–4, 26.

C. Ground 1: Anticipation by Slater

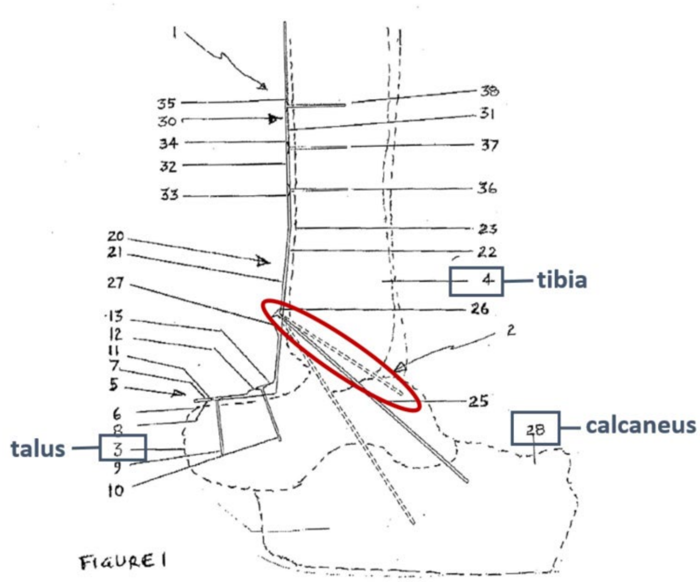
Petitioner contends that claims 1–5, 9–13, and 16–19 are anticipated by Slater. Pet. 15–36. For the independent claims, Petitioner provides a more detailed analysis on claim 1 and substantially cross-references the analysis on claim 1 when addressing claims 10 and 16. *Id.* at 16–27 (analysis for claim 1), 33–36 (combined analysis on claims 10 and 16).

Patent Owner raises multiple counterarguments. PO Resp. 25–40.

As do the parties, our discussion below focuses largely on claim 1. *See*, *e.g.*, Pet. 33–36 (Petitioner characterizing the elements of claims 10 and 16 as being "nearly identical" or "similar" to the elements of claim 1). Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 are anticipated by Slater. Our analysis follows.

1. Petitioner's Contentions

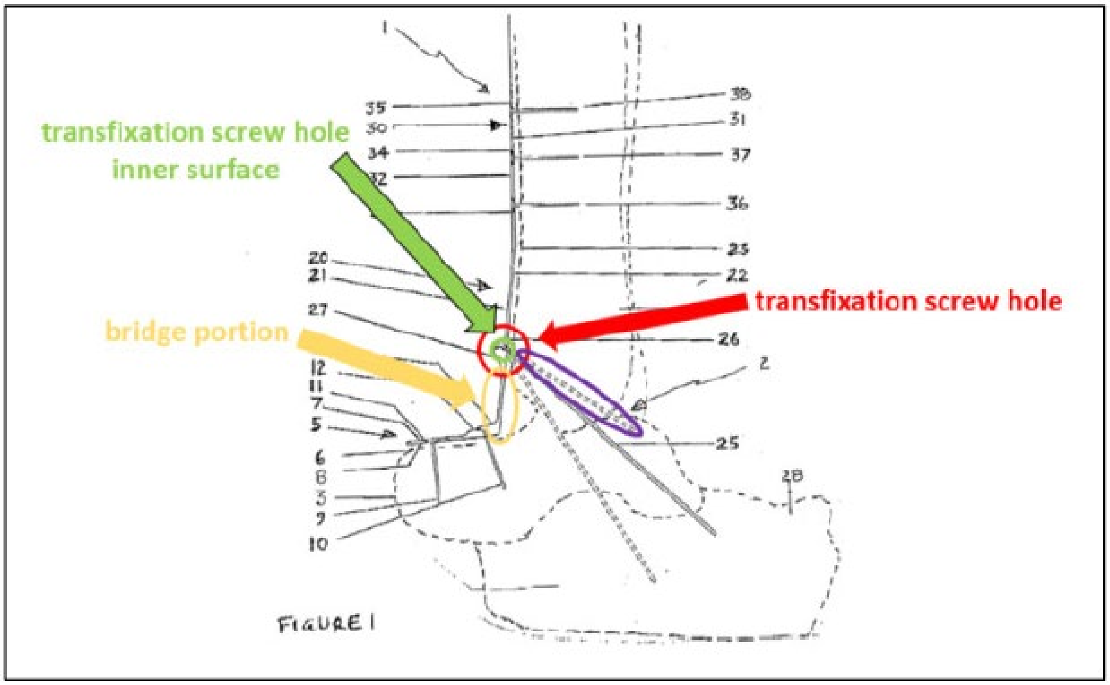
Petitioner argues that, if claim 1's "preamble is limiting, Slater [discloses] a system for securing two discrete bones together across a joint between the two bones." Pet. 16. In support, Petitioner provides an annotated version of Slater's Figure 1, reproduced below.



Id. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* Petitioner contends that Figure 1 shows an embodiment where the fusion plate is secured to three discrete bones (tibia, talus, and calcaneus) across two joints between those bones, and also an embodiment where the plate is secured to only two bones (tibia and talus) across one joint between those bones—the latter evidenced by the screw path in the red oval noted above. *Id.* Petitioner supports this interpretation of Slater with Dr. Gall's testimony. Ex. 1002 ¶ 121.

Petitioner further contends that Slater discloses claim 1's elongate spine and first and second ends, as well as a bridge portion between the ends that has a depth (or thickness) greater than the first and/or second end portions. Pet. 17–23 (citing Ex. 1002 ¶¶ 122–128). Petitioner contends that those limitations are disclosed in, for example, Slater's Figure 1 and the features depicted therein. *Id.*

Petitioner also contends that Slater discloses claim 1's transfixation screw hole and transfixation screw limitations. Pet. 23–27. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



Id. at 24–25. Petitioner's annotation to Figure 1, above, identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). *Id.* (citing Ex. 1002 ¶ 130). According to Petitioner, "Figure 1 shows three separate exemplary angles for transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3)." *Id.*; Ex. 1005, Fig. 1.

Petitioner contends that Slater discloses a transfixation screw with a head and shaft as claimed. Pet. 25–26. Again, referencing Slater's Figure 1, Petitioner contends that Slater discloses a screw configured to contiguously

extend through a first bone (tibia 4), through a joint (2), and into a second bone (talus 3). *Id.* at 26 (citing Ex. 1005, Fig. 1, 11:19–25, 13:21–24). For claim 1's recitation about the screw being configured "so as to absorb tensile load" and "transferring the tensile load" from the second bone through the screw into the head and bridge, Petitioner contends that Slater satisfies those elements as well. *Id.* at 26–27. According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the talus through the screw into the screw head and plate's bridge portion as claimed. *Id.* Petitioner explains that "[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between." *Id.* Petitioner provides testimony from Dr. Gall to support this understanding of Slater's teachings and the functionality of Slater's plate when fixed to the tibia and talus as shown. *Id.* (citing Ex. 1002 ¶ 131).

2. Patent Owner's Response

Patent Owner contends that "nothing in Slater expressly or inherently discloses transferring the tensile load from the second bone through the fixation screw head and into the bridge portion of the plate." PO Resp. 37. Specifically, Patent Owner contends that Petitioner and Dr. Gall improperly assume that Slater discloses a "vise" configuration to transfer tensile load from the second bone, through the screw and into the bridge portion. *See id.* According to Patent Owner, and its declarant Mr. Sommers, Dr. Gall's assumption depends on the assumption that the threads of Slater's screw 70 would only engage the second bone (the talus) in Slater's two-bone

embodiment, but Slater lacks any disclosure to support this assumption. *See id.* at 36–37 (citing Ex. 2002 ¶ 107; Ex. 2003, 44:21–45:15). Patent Owner argues that Slater does not expressly or inherently disclose Petitioner's "vise" construct, and that Slater fails to disclose how an undisclosed embodiment using the vise approach would transfer tensile load. *Id.* at 40–41 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶ 109). Patent Owner further contends that Dr. Gall's opinion lacks citations of support to Slater, and any reliance on Slater's finite element analysis lacks support because the test data does not state how the transfixion screw was affixed or loaded, or how many bones it penetrated. *Id.* at 41–42 (citing Ex. 1002 ¶¶ 125, 154; Ex. 2002 ¶¶ 117–119; Ex. 2003, 92:24–93:7).

3. Petitioner's Reply

Petitioner responds that Slater discloses the "vise" configuration because it uses a lag screw "through an angled formation in the bone plate to cross a joint or joints where the screw head is in 'cooperation' with the screw hole," creating a well-known "lag effect" to compress bone parts and absorb tensile load. Pet. Reply 13–14 (citing Ex. 1002 ¶¶ 131, 151–153, 165, 182; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1027 ¶¶ 34–45; Ex. 1030, 68:17–70:3, 106:19–107:17; Ex. 2003, 46:23–48:4). Petitioner argues that Mr. Sommers conceded that you only want threads in the second bone, and described transfer of tensile load in the '716 patent in the same manner that Dr. Gall describes Slater transfers tensile load. *Id.* at 14–15 (citing Ex. 1002 ¶¶ 131, 165, 182; Ex. 1027 ¶¶ 42–43; Ex. 1030, 67:23–68:7, 74:6–25, 77:14–22). Petitioner also argues that "Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate." *Id.* at 15

(citing Ex. 1005, 17:14–20:26; Ex. 2003, 92:17–93:7; Ex. 1027 ¶ 44). According to Petitioner, Slater's testing simulated in vivo loading conditions and show that "at least some tensile load is necessarily distributed from the angled screw formation to the bridge portion." *Id.* (citing Ex. 1005, 17:20–21, 19:1–6; Ex. 1027 ¶¶ 44–45; Ex. 1030, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. Analysis

Independent claim 1 recites

> a transfixation screw comprising a head configured to abut the inner surface of the transfixation screw hole and a shaft configured to contiguously extend through the first discrete bone, through the joint, and into the second discrete bone *so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring the tensile load from the second discrete bone, through the screw into said head and said bridge portion*.

Ex. 1001, 12:56–64 (emphasis added). Independent claim 10 recites

> a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone, *enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge.*

Id. at 13:50–59 (emphasis added). Independent claim 16 recites

> a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second

> bone, *enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge.*

Id. at 14:36–45 (emphasis added). We will refer to these limitations collectively as the "transfer of tensile load" limitations. The parties dispute whether Slater expressly or inherently discloses these limitations.

We first address Petitioner's argument that Slater discloses a "vise" configuration, which relies on Petitioner's argument that Slater uses a lag screw with threads on its end that only engage the second bone in Slater's two-bone configuration. *See* Pet. 26–27; Reply 12–15. We are not persuaded by Petitioner's argument because Slater does not expressly or inherently disclose how its lag screw threads interact with the first and second bone. Slater's Figure 4 "shows an elevation view of a second screw type 70" having "a longer shank to increase depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone." Ex. 1005, 12:32–13:3. This description of screw type 70 in the *three*-bone configuration does not state that the screw *only* engages the third bone, the calcaneus bone, and describes the "majority of the shank" as "slid[ing] through" holes in the first two bones without stating that none of the threads engage a portion of, for example, the end of the second bone adjacent the third bone. *See id.* More importantly, even if this portion of Slater describes a *three*-bone embodiment where the threads only engage the third bone, Slater provides insufficient support for Petitioner's position that the threads of screw type 70 only engage the second bone in Slater's *two*-bone embodiment, which Petitioner relies on as the anticipatory embodiment of Slater. *See* Pet. 16; Ex. 1002 ¶ 121 (arguing that Slater's Figure 1 shows

two-bone embodiment). Slater contains no details on this aspect of its alternative two-bone embodiment, such that the threads of the screw may engage the end of the first bone adjacent the second bone and still provide satisfactory results. At best, Petitioner and Dr. Gall's related testimony establish that it would have been desirable, and perhaps obvious, to have the threads of screw type 70 only engage the second bone in Slater's two-bone embodiment to create a vise-like configuration that transfers tensile load as claimed, but that does not establish that Slater expressly or inherently discloses such an embodiment to satisfy the anticipation standard.

We next address Petitioner's reliance on Slater's finite element analysis tests. *See* Reply 13–15. Petitioner did not rely on this aspect of Slater in the Petition, and raised the argument for the first time in Reply. *Compare* Pet. 26 *with* Reply 15; Sur-Reply 6–7. Setting aside the propriety of failing to rely on this aspect of Slater in the Petition, we are not persuaded by Petitioner's argument and evidence for two reasons. First, Petitioner appears to still rely on its argument that Slater discloses a "vise" configuration, and argues that the testing confirms the transfer of tensile load. *See* Reply 12–13 (relying on "vise" argument), 15 ("Slater describes in-vivo studies that confirm tensile load is transferred from the bone to the screw and to the bone plate."). Petitioner does not appear to argue that even if we find that Slater does not disclose the "vise" configuration and does not necessarily disclose screw threads that only engage the second bone, that the testing alone shows that Slater discloses the limitation. Reply 15. Accordingly, we do not find the testing argument persuasive due its link to arguments we find unpersuasive for the reasons discussed above.

Second, Patent Owner correctly points out that Slater provides inadequate information to conclude that the testing results apply to Slater's two-bone configuration such that we can conclude that Slater's two-bone embodiment results in the claimed transfer of tensile load to the plate's bridge. *See* PO Resp. 37–38 (citing Ex. 1002 ¶¶ 131, 165; Ex. 2002 ¶¶ 106–107; Ex. 2003, 44:21–45:15). Slater's tests merely simulate the response of its plate to certain loads, and do not purport to show actual loading of the plate on a patient in either the three-bone or two-bone embodiments. Ex. 1005, 17:14–23 (referring to analysis of simulated in-vivo performance and "anticipated loadings" of the plate). Slater also emphasizes that the simulations only apply to "a plate of the particular type and geometry tested" and that "plates with different geometry and dimension . . . may result in different measured loadings and plate response" and "will be likely to have different load capacity results." *Id.* at 20:13–23. Based on the lack of detail as to how Slater's simulations would apply to its two-bone embodiment, and Slater's warning that the simulated results only apply to the specific plate tested, we agree with Patent Owner that Slater's simulated testing does not establish that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1, 10 and 16.

Finally, for similar reasons, we find the testimony of Patent Owner's declarant Mr. Sommers more credible and persuasive than the testimony of Petitioner's declarant Dr. Gall. For example, Dr. Gall opines that Slater discloses a vise configuration, but fails to point to any portion of Slater disclosing that configuration with respect to the two-bone embodiment. *See* Ex. 1002 ¶ 131; Ex. 1027 ¶¶ 37–46. Again, this testimony may establish the desirability of such a configuration and that one of ordinary skill in the art,

when using Slater's plate, may do so in the manner Dr. Gall proposes, but that does not establish that Slater expressly or inherently discloses a vise-like configuration due to threaded engagement with only the second bone in Slater's two-bone embodiment. We view the testimony of Mr. Sommers as more credible because it more accurately tracks Slater's disclosures. *See* Ex. 2002 ¶¶ 81–82 (opining that Slater "does not describe whether there would also be threads" in the second of the three bones in the three-bone embodiment, in practice the threads may engage multiple bones, and Slater does not illustrate or describe how the screw would be used on a two-bone configuration), 75, 105–117 (opining that Slater fails to disclose the transfer of tensile load limitations).[10]

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claims 1, 10 and 16, and, therefore does not prove, by a preponderance of the evidence, that Slater anticipates either of claim 1, 10 or 16.

Petitioner's challenge to dependent claims 2–5, 9, 11–13, and 17–19 as anticipated by Slater is substantially similar to its analysis of independent claims 1, 10 and 16, which relies on Petitioner's predicate analysis on the independent claims. Pet. 27–32, 36. That analysis suffers from at least the same shortcomings discussed above for independent claims 1, 10 and 16.

[10] We are also unpersuaded by Petitioner's arguments based on the alleged similarity between the description Mr. Sommers provides of how the '716 patent shows the transfer of tensile load and Dr. Gall's description of how Slater transfers tensile load. *See* Reply 16–17. It is hardly surprising, and largely irrelevant, that Petitioner's declarant would describe the prior art in a manner consistent with the Patent Owner or its declarant's description of the how the challenged patent works. That similarity alone does not establish that the prior art expressly or inherently discloses the limitation in question.

Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 are anticipated by Slater.

D. Ground 2: Obviousness over Slater and Weaver

Petitioner contends that claims 6 and 8 are unpatentable for obviousness over Slater and Weaver. Pet. 36–39. Claims 6 and 8 depend from claim 1 and add, respectively, that transfixation screw hole or at least one attachment point includes features that lockably engage the transfixation screw head or locking bone screws. Ex. 1001, cl. 6, cl. 8. Petitioner alleges that those locking features are disclosed in Weaver and it would have been obvious to add them to Slater's plate to provide a more secure fixation between the screws and the plate. Pet. 37–38; Ex. 1002 ¶¶ 191–192, 194–196. Petitioner otherwise relies on its anticipation analysis for claim 1 discussed above. *Id.* at 36.

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Slater and Weaver.

E. Ground 3: Anticipation by Falkner

Petitioner contends that claims 1–3, 6, 8–12, and 16–18 are anticipated by Falkner. Pet. 39–58. As with Slater and Ground 1, Petitioner provides its analysis on claim 1 and largely cross-references that analysis for claims 10 and 16. *Id.* at 39–49 (claim 1), 55–57 (combined analysis on

claims 10 and 16). Patent Owner raises multiple counterarguments. PO Resp. 45–54.

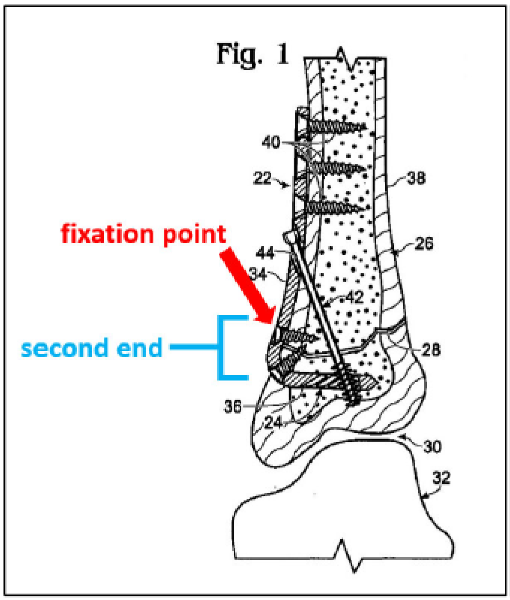
Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–12, and 16–18 are anticipated by Falkner. Our analysis follows.

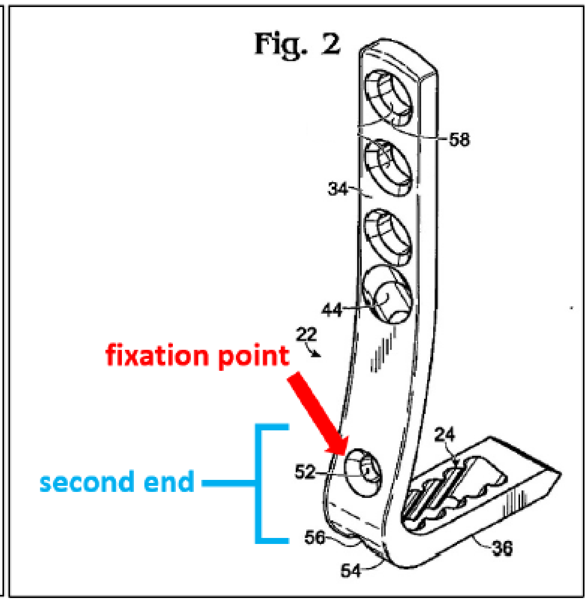
1. Petitioner's Contentions

Petitioner alleges that Falkner discloses claim 1's preamble. Pet. 39–40. According to Petitioner, although Falkner's Figure 1 shows a plating system for fixing a single bone having a fracture, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. Ex. 1006 ¶¶ 21, 28. Petitioner also cites Falkner's disclosure that, in other examples, "plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21.

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 41 (citing Ex. 1002 ¶ 201). And, Petitioner argues, "the inner surface [of the plate] would be configured to substantially conform with a geometry of the first discrete bone (tibia 26)." *Id.* at 42 (citing Ex. 1006 ¶¶ 23, 34; Ex. 1002 ¶ 202). According to Petitioner, this configuration would meet claim 1's "elongate spine" and "first end" limitations. *Id.* at 40–43.

For claim 1's "second end" limitations, Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.

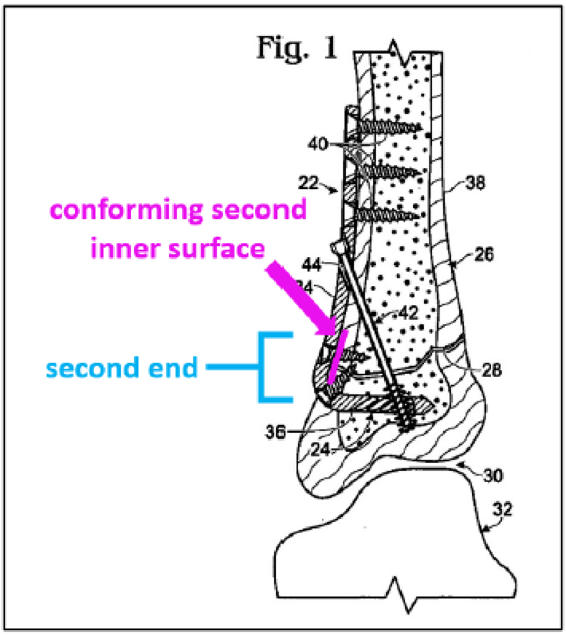




Pet. 43 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which bracketed segment Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.*

With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia 26 and talus 32 . . . bone screw 40 may be placed into the second discrete bone . . . (talus) through the opening 52 at the second end of the plate 22." *Id.* at 44 (citing Ex. 1002 ¶

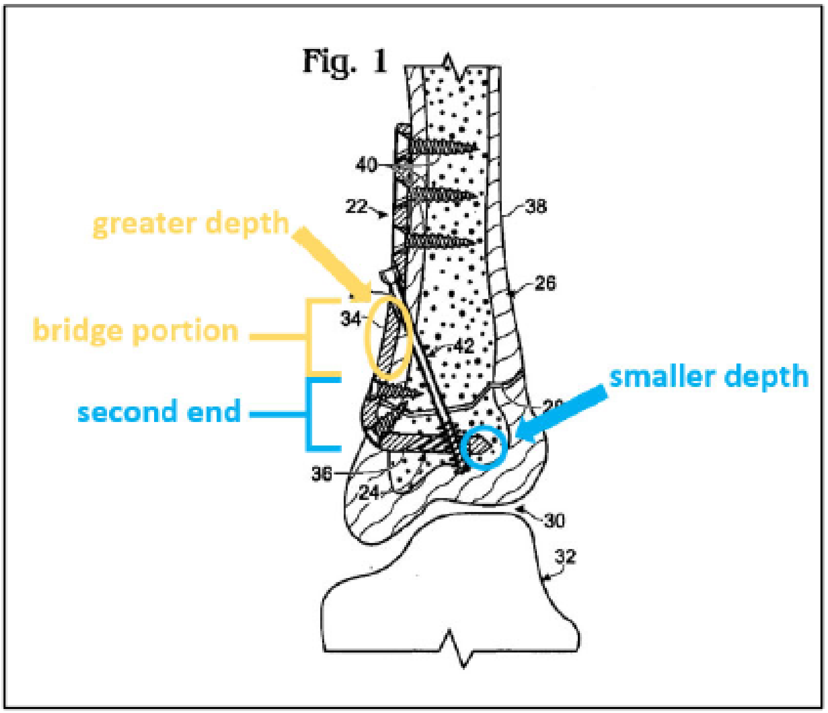
203). And, referencing another annotated version of Figure 1 (reproduced below), Petitioner contends that "the second inner surface would be configured to substantially conform with a geometry of the second discrete bone (talus 32)." *Id.* at 44–45 (citing Ex. 1002 ¶ 204).



Id. at 44; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner's plate attached to the tibia, including Petitioner's blue bracket designating the same alleged "second end," but here Petitioner annotates (with purple arrow, line, and text) an alleged conforming "second inner surface." Pet. 44. Petitioner's position appears to be that this purple portion depicted in Figure 1 would be adapted and thus, configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. *Id.* at 44–45.

Turning to claim 1's bridge portion and the requirement that the bridge portion have a depth or thickness greater than a portion of the first or

second ends, Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 45–46. This annotated figure is reproduced below.



Id. at 46; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, above, shows the same plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval, bracketing, and text. Pet. 46. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" has a "greater depth." *Id.* This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as having a "smaller depth," which Petitioner highlights with a blue circle, arrow, and text. *Id.* From this, Petitioner argues that "at least a portion of the bridge

portion has a depth (i.e., thickness) greater than at least a portion of the depth of the second end." *Id.* (citing Ex. 1002 ¶ 206).

For the transfixation screw hole and transfixation screw limitations of claim 1, Petitioner cites Falkner's oblique opening (44) in external plate portion (34), and threaded faster (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate's internal plate portion (36). Pet. 47–49. According to Petitioner, in a configuration where Falkner's plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* at 48. And, in that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred from the talus through the screw and into the bridge portion. *Id.* at 49 (citing Ex. 1002 ¶ 209). In support, Petitioner cites Falkner's teaching that "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." Pet. 49 (quoting Ex. 1006 ¶ 71).

2. Patent Owner's Response

Patent Owner makes three main arguments with regard to independent claims 1, 10, and 16. PO Resp. 40–54. For purposes of this decision, especially given the parties' overlapping arguments, we focus on claim 1.

First, Patent Owner argues that Falkner fails to disclose a system for securing two discrete bones together across a joint between the two bones. *Id.* at 46–48. Patent Owner contends that Falkner's plate is not designed to secure the two discrete bones across a joint and further contends that "[t]o

make a Falkner-type plate that crosses a joint would require extensive modification." *Id.* at 46–47.

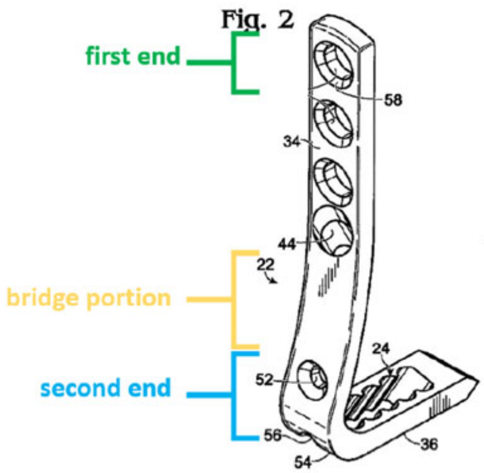
Second, Patent Owner argues that Falkner fails to disclose a "second end" that includes a "fixation point" and an "inner surface configured to substantially conform with a geometry of the second discrete bone" as required by the claims. *Id.* at 48–50. Patent Owner argues that what Petitioner identifies as the "second end" of Falkner's plate is inside the bone and therefore does not conform to the geometry of the second bone. *Id.* at 50. Patent Owner further contends that,

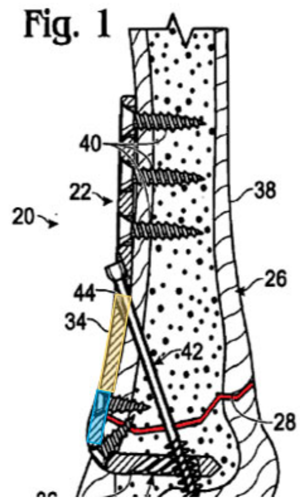
> With the interior portion of the Falkner blade-plate unable to conform to the geometry of the second discrete bone, the Petition relies on Dr. Gall, rather than the disclosure of Falkner, to conclude that "the plate 22 would have been placed across the joint 30 and the second inner surface would have been configured to substantially conform with a geometry of the second discrete bone (talus 32)." (Ex. 1002, ¶ 204 (emphasis added)). That something "would have been configured" is the hallmark of obviousness, and perhaps recognizing this after the fact, Dr. Gall at his deposition seemingly changed course and indicated that a Falkner plate spanning a joint would still include the portion that is interior to the bone. (Ex. 2003 86:11–15). Therefore, Falkner fails to disclose a second end configured to "substantially conform with a geometry of the second discrete bone."

PO Resp. 50–51.

Third, Patent Owner contends that Petitioner's modified version of Falkner's plate does not have any portion configured to span across the bridge portion. *Id.* at 52–54. Patent Owner explains that even if the Falkner plate can be moved across the joint, the plate would cross the "second end", not the bridge portion. *See id.* at 52 ("the *Falkner* blade-plate 'bridge portion' that Petitioners rely upon would not cross the joint at all"). To illustrate that point, Patent Owner references and compares Dr. Gall's

annotated image of Falkner's figure 1, shown below on the left, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the right.





Id. at 53 (citing Ex. 1006, Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 205); Ex. 2002 ¶ 145 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as it would be applied to a bone. Ex. 1001, 3:16–17. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* at 2:17–21. Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioner identifies as the "second end." PO Resp. 53–54. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has identified highlighted in blue just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* (citing Ex. 2002 ¶ 146). Thus, according to Patent Owner, the Falkner plate does not cross the bone discontinuity in Figure 1.

3. Petitioner's Reply

In its Reply, Petitioner responds that "Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the [S]pecification 'may be positioned on and/or in any suitable bone(s) to span any natural or artificial discontinuity within a bone or between bones.'" Reply 17–18 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1028. Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes' testimony who believes that "Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***." Reply 18–19 (citing Ex. 1028, ¶¶ 19–20, 25–36). Instead, Petitioner cites to Dr. Holmes who describes a procedure whereby:

> surgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus" to help create a biomechanically stable joint for fusion. (Ex.1028, ¶¶31–32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Reply 19. Petitioner contends that Falkner "expressly contemplates and enables a POSITA to use its bone plate for joint fusion, and teaches all of the structural limitations set forth in the challenged claims." *Id.* at 20.

4. Patent Owner's Sur-Reply

In its Sur-Reply, Patent Owner responds that Falkner does not disclose the modifications required to anticipate the challenged claim and instead, the Petitioner relied heavily on Dr. Holmes' testimony on how the

plate could have been modified. Sur-Reply 17. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that the theory of anticipation raised in the Petition is obviousness in disguise." *Id.* at 18. Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-Reply 18–22 ("the extensive modifications required for Falkner's plate to be used across a joint, go beyond what reasonably could be anticipation")

5. Analysis

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. Petitioner's position does not prevail for at least the reasons set forth on pages 45–54 of the Patent Owner Response and pages 18–22 of the Sur-Reply, which we adopt. In particular, we agree with Patent Owner that Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed. PO Resp. 45–46; Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured as claimed would apparently require at least some level of redesign or modification. Those might be simple, even arguably obvious, changes for the person of ordinary skill in the art in light of Falkner and its overall teachings, but Petitioner's challenge is based on anticipation. Indeed, Petitioner's and Dr. Gall's repeated invocation of how Falkner's plate, if

used in the hypothetical joint-spanning context, "would have been" configured rings of obviousness, not anticipation. *See, e.g.*, Ex. 1002 ¶¶ 202–204.

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But there is a dearth of detail about such a hypothetical plate's actual design. On this record, it appears to us that making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met (e.g., surfaces of the first and second ends that conform to a bone geometry, and a thicker bridge portion relative to the ends). The person of ordinary skill in the art might, for example, decide to conform some or multiple portions of the hypothetical bone plate to the exterior geometries of multiple bones, such as the tibia and talus. Such a design is even arguably suggested elsewhere in Falkner, where it discloses that bone plates "may be sized and shaped to conform to particular portions of a bone (or bones)" or "may be contoured generally to follow an exterior surface of a target bone (or bones)" (Ex. 1006 ¶¶ 33–34). But, here again, our concern is that such a theory drifts from anticipation—a doctrine still rooted in "strict identity"[11]—to obviousness.

Moreover, we note that Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate

[11] *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002).

that appears to be close to the middle of the plate and characterizes that portion as a "second end." Pet. 43. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id.* at 46. Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its anticipation position, while purporting to modify other portions of that embodiment (e.g., contouring the plate to a particular bony geometry) in order to render it suitable for a different attachment across multiple bones.[12] Such picking and choosing is indicative of obviousness.

Regarding independent claim 10, Petitioner acknowledges that many of the limitations recited in independent claims 1, 10, and 16 are "nearly identical" with exceptions accounted for in its analysis set forth in the Petition. Pet. 54–56. Those differences between claim 1 and 10 identified by Petitioner do not cure the deficiencies discussed above with regard to claim 1. Thus, for at least the same reasons as discussed with respect to

[12] As a further example, Petitioner identifies opening (52) in Falkner's plate in Figure 1 as the alleged fixation point on a second end of the plate as claimed. Pet. 43. But, as described in Falkner, opening (52) and its corresponding bone screw is fixed on the *same side* of the bone discontinuity (fracture) as the plate portion Petitioner identifies as the plate's first end. Ex. 1006, Fig. 1. Inasmuch as a joint is simply another bone discontinuity in Falkner, Petitioner asserts, with minimal explanation, that a screw would have been placed through opening (52) to secure a second bone (e.g., talus) on the *opposite side* of the joint relative to the plate's first end when the plate is modified for use in this different context. *Id.* at 44; Ex. 1002 ¶ 202.

claim 1, we are not persuaded on the current record that Falkner anticipates claim 11.

Petitioner's challenge to dependent claims 2–3, 6, 8–9, 11–12, and 17–18 as anticipated by Falkner relies on Petitioner's predicate analysis on the independent claims. Pet. 49–54, 57. That analysis suffers from at least the same shortcomings discussed above for independent claims 1, 10, and 16.

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, 8–12, and 16–18 are anticipated by Falkner.

F. Ground 4: Obviousness over Falkner and Arnauld

Petitioner argues that dependent claims 4, 5, 13, and 19 would have been obvious over Falkner and Arnauld. Pet. 58–61. Petitioner's argument under Ground 4 relies on Petitioner's predicate anticipation challenge under Ground 3 for those claims from which claims 4, 5, 13, and 19 depend. *Id.* Petitioner relies on Arnauld under Ground 4 only for allegedly teaching certain transfixation angles encompassed by claims 4, 5, 13, and 19.

We determine that Ground 4 suffers from at least the same shortcomings as discussed above for Ground 3. Also, Petitioner contends a person of ordinary skill in the art would have been motivated to modify Falkner's bone plate to provide a plate specifically for use with a metatarsophalangeal joint and, in so doing, select the transfixation angles disclosed in Arnould. Pet. 58–61. Petitioner's anticipation analysis of Falkner, however, focused on the plate of Falkner's Figure 1, allegedly designed to render it suitable for use with the tibia and talus. Petitioner provides no sufficient explanation as to how this plate would be now

designed and configured for an entirely different set of bones and joint—the metatarsophalangeal joint—and still meet all the claim limitations of the underlying independent claims. *Id.* Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Falkner and Arnould.

G. Ground 5: Obviousness over Arnauld and Slater

Petitioner argues that claims 1–5, 9–13, and 16–19 would have been obvious over Arnauld and Slater. Pet. 61–77. For independent claims 1, 10, and 16, like Petitioner, our analysis focuses on claim 1. *Id.* at 74–76 (relying substantially on analysis for claim 1 for claims 10 and 16). Petitioner also contends that a person of ordinary skill in the art "would have been motivated to modify the bone plate of Arnauld with the thickened bridge portion of [] Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." Pet. 67.

Patent Owner raises multiple counterarguments. PO Resp. 56–60. In particular, Patent Owner contends that thickening the portion of the Arnould plate Petitioner identifies as the bridge portion, "junction zone 14," would be contrary to the purpose of Arnould's disclosure. PO Resp. 57. Patent Owner further contends that Arnould in view of Slater fails to teach the elements of "a transfixation screw hole disposed along the spine." *Id.* at 59–61.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 would have been obvious by the combination of Arnould and Slater. Our analysis follows. For independent claims 1, 10, and 16, like Petitioner, our analysis focuses on claim 1.

Pet. 74–76 (relying substantially on analysis of claim 1 for claims 10 and 16).

1. *Independent Claim 1*

a) *Whether there is Motivation to Combine Arnould and Slater*

Petitioner contends that "Arnauld discloses each and every element of independent claim 1 except" the element "which recites 'at least a portion of said bridge portion having a depth greater than at least a portion of the depth of either the first end or the second end.'" Pet. 61–62; Ex. 1002 ¶ 282. For that missing limitation, Petitioner turns to Slater, which Petitioner argues discloses a thicker bridge portion. Pet. 62. Petitioner argues that a person of ordinary skill in the art "would have been motivated to modify the bone plate of Arnould with the thickened bridge portion [] of Slater in order to strengthen the bone plate in the region of the bone plate spanning across the joint." *Id.* at 67 (citing Ex. 1002 ¶ 290); *see also* Reply 25 (there is motivation to combine Arnould and Slater "to strengthen the plate in the area that experiences the highest stress—the portion near the MTP joint.") (citing Ex. 1002 ¶¶ 290, 333, 351; Ex.1027 ¶¶ 52–54).

Petitioner also explains that "[w]ith the use of a plate bender, a surgeon can adjust even a thickened portion of an MTP plate to conform to the variable anatomy of the metatarsophalangeal joint." Reply 25 (citing Ex. 1028 ¶ 34). Moreover, Petitioner contends that

> *Arnould* expressly contemplates a surgeon modifying the angle between the metatarsal and phalangeal parts of the bone plate to accommodate varying degrees of dorsiflexion. Bending the plate at the bend line weakens the plate, so thickening the plate at the bend line would improve the strength of the *Arnould* plate.

Id. (citing Ex. 1008 ¶¶ 20, 38; Ex. 1027 ¶ 56).

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that the proposed motivation is contrary to the disclosure of Arnould for two reasons. PO Resp. 56–58. First, thickening the specified portion in Arnould "would be contrary to the purpose of Arnould's disclosure" because "it is designed in a specific manner to allow a surgeon to bend the plate at that junction zone to conform the plate in situ to a patient's bone anatomy." PO Resp. 57–58; Ex. 1008 ¶ 38; Ex. 2002 ¶¶ 155–157; *see also* Ex. 2002 ¶ 157 (Arnould's "junction zone 14" is "purposely not strengthened to allow for bending by the surgeon at time of implantation.") (citing Ex. 1008 ¶ 38).

Second, there is no motivation to modify the plate in Arnould "[b]ecause the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest." PO Resp. 58. Rather, Arnould discloses that "the highest loading occurs in the cross-joint screw itself: 'this screw essentially, **if not exclusively**, takes up the bending stress generated during the patient's walking.'" *Id.* (quoting Ex. 1008 ¶ 6; citing Ex. 2002 ¶¶ 70, 165). "Because the highest stress of the Arnould plate does not occur at the junction zone 14 as Petitioners suggest, there would be no reason to modify that portion of the plate to accommodate additional stress as taught in Slater." *Id.*

b) Whether Arnould in view of Slater Fails to Teach a Transfixation Screw Hole Disposed Along the Spine

Claims 1, 10 and 16 of the '716 patent specify that the "transfixation screw hole [is] disposed along the spine" of the plate. Ex. 1001, cl. 1, 10, 16. The Petition relies solely on Arnould for this element. Pet. 67.

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position, which we adopt as our own. In particular, we agree with Patent Owner that Arnould in view of Slater fails to teach or suggest a transfixation screw hole to be deposed along the spine. PO Resp. 57–59. The alleged transfixation screw hole of Arnould is a "through-hole 25 (at the end of leg 20[)] . . . [and] is not disposed on the spine, but part of a separate leg piece that extends off the spine." *Id.* at 59. The following annotated version of Arnould's Figure 1 illustrates that point.

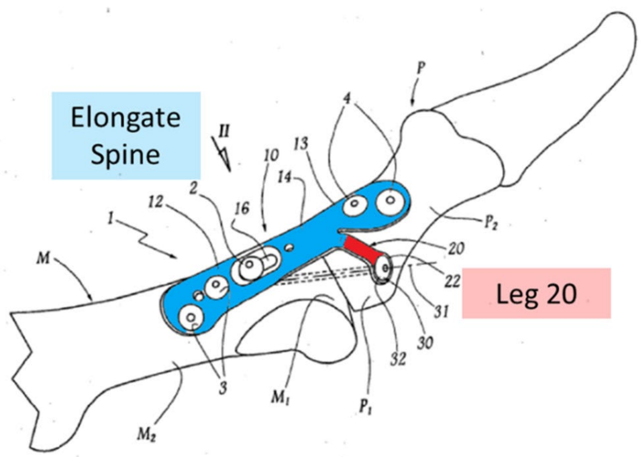


Fig. 1

Id. at 59; Ex. 1008, Fig. 1. The annotated version of Arnould's Figure 1, above, shows plate (1) having a plate body (10) attached to the metatarso-phalangeal bones and joint, and Patent Owner has highlighted in blue the plate's longitudinal body, which Patent Owner calls the "Elongate Spine." PO Resp. 59. In red, Patent Owner highlights leg (20), which extends downward from the longitudinal side of the plate body near the plate's midsection. *Id.*

Arnould discloses that leg (20) is meant to wrap around the bone and is located vertically below the plate body, which is evident with reference to

Figure 1 above. Ex. 1008 ¶ 23; Ex. 2002 ¶¶ 161, 172. Furthermore, as noted by Patent Owner:

> Arnould fails to disclose or suggest disposing screw 30 along the spine; and there is no reason in view of Arnould to locate a transfixation screw hole along the spine as required by the claims of the '716 patent because the explicit advantage of Arnould is that the leg and screw were moved off the spine to generate "a significantly higher capacity to resist bending stresses than the plate body due to its structure and **implantation zone**."

PO Resp. 60 (citing Ex. 1008 ¶ 6 (emphasis added); Ex. 2002 ¶ 162).

We have considered but are not persuaded by Petitioner's Reply argument that

> Patent Owner incorrectly re-writes "disposed along the spine" as "disposed on the spine," and improperly narrows the term "spine" to mean the center line of the plate. (POR, 59). The claim language nowhere equates the "elongate spine" with the center line of the plate.

Reply 26. Rather, we agree with Patent Owner that

> Something cannot be both along the body (or in the case of the claims, the spine) and below it. Petitioners also ignore the rest of claim 1, which requires that "the bridge portion [of the elongate spine] [be] configured to span across the joint," and that "a transfixation screw hole [is] disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct the transfixation screw through the transfixation screw hole such that the transfixation screw extends through the bridge portion at a trajectory . . . [.]" (Ex. 1001, cl. 1). *Given that leg 20 is located below the body of the plate and does not cross the joint, it cannot be the claimed bridge portion.*

Sur-Reply 24 (emphasis removed; emphasis added).

c) Analysis of Remaining Claims

Petitioner's analysis of independent claim 10 as obvious over Arnould and Slater is essentially the same as its analysis of claim 1. Pet. 77–78. That

analysis suffers from at least the same shortcomings discussed above for claim 1. The same is true of Petitioner's analysis of dependent claims 2–5, 9, 11, 12, and 13, which relies on Petitioner's predicate analysis on the independent claims. *Id.* at 69–73, 75–76.

2. Conclusion

For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 would have been obvious over Arnould and Slater.

H. Ground 6: Obviousness of Claims 6 and 8 over Arnould, Slater, and Weaver

Petitioner argues that claims 6 and 8 would have been obvious over Arnould and Slater, in further view of Weaver. Pet. 76–77. Petitioner's reliance on Weaver here is substantially the same as for Ground 2—citing Weaver's screw locking features and reasons to add them. *Id.* Claim 6 and 8 depend, however, from claim 1 and Petitioner's challenge under Ground 6 presumes Petitioner's predicate success on Ground 5. *Id.* (asserting that "independent claim 1 is rendered obvious by Arnould in view of Slater" before turning to claims 6 and 8).

We have considered Petitioner's arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to the combination of Arnould and Slater with respect to independent claim 1, from which claims 6 and 8 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 6 and 8 would have been obvious over Arnould, Slater, and Weaver.

III. CONCLUSION

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–5, 9–13, 16–19	102	Slater		1–5, 9–13, 16–19
6, 8	103	Slater, Weaver		6, 8
1–3, 6, 8–12, 16–18	102	Falkner		1–3, 6, 8–12, 16–18
4, 5, 13, 19	103	Falkner, Arnould		4, 5, 13, 19
1–5, 9–13, 16–19	103	Arnould, Slater		1–5, 9–13, 16–19
6, 8	103	Arnould, Slater, Weaver		6, 8
Overall Outcome				1–6, 8–13, 16–19

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–6, 8–13, and 16–19 of the ’716 patent are not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Paper 46
Date: March 14, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01452
Patent 9,763,716 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*, concurring.

I concur that Slater does not anticipate claims 1–6, 8–13, and 16–19, and reach that result for the following additional reason.

Independent claim 1 recites a "transfixation screw hole comprising *an inner surface configured to direct the transfixation screw* through the transfixation screw hole *such that* the transfixation screw extends the bridge portion *at a trajectory configured* to pass through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone once the plate is placed across the joint." Independent claims

10 and 16 recite a substantially similar element. A dispute between the parties is whether the claim recitation for "an inner surface configured to direct the transfixation screw . . . at a trajectory" is taught by Slater.

To that point, Petitioner contends that Slater identifies openings 26 and 93 that "each receive a fixation screw that passes through those openings so that the screw is implanted at an angle." Pet. 24 (citing Ex. 1005, 11:19–21, 13:21–24, Figs. 1, 7). More specifically, Petitioner contends that Slater's "transfixation screw hole (26 or 93) . . . comprises an inner surface (unnumbered in Slater's drawings) configured to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends through the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first discrete bone (tibia 4), a portion of the joint (2), and a second position on the second discrete bone (talus 3)" once the plate (1 or 80) is placed across the joint. *Id.* (citing Ex. 1002 ¶¶ 129–130; Ex. 1005, 11:19–25, 13:21–25).

In its Response, Patent Owner directs our attention to Figure 1 of Slater, and contends that this Figure "depicts, in phantom, the use of a screw that passes through the tibia and terminates in the talus." PO Resp. 10 (citing Ex. 2002 ¶ 55). "The hole that the screw 25 passes through is constructed in a manner that allows the angle of the screw to be modified as the plate is affixed to the ankle joint." *Id.* at 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). "This hole is described as 'slotted,' meaning that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles." *Id.* (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8); *see also* Ex. 1005, 16:28–30 ("One significant advantage of the plate described is the oblique

screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required."), Fig. 1.

Furthermore, Patent Owner notes that Slater "provides no detail regarding the structure of the inner surface of the hole" because a surgeon using Slater's plate "determines the path in situ with a range of options available." PO Resp. 35 (citing Ex. 1005, Fig 1; Ex. 2002 ¶ 97). That is, "Slater describes a plate that intentionally allows for varied angles through the same hole." *Id.* at 35–36 (citing Ex. 1005, 16:28–30 ("[o]ne significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required"); Ex. 2002 ¶ 103)). Patent Owner contends that, because the hole identified by Petitioner as Slater's transfixation screw hole allows for varied angles through the same hole, Slater fails to disclose a transfixation screw hole having "an inner surface configured to direct the transfixation screw through the transfixation screw hole . . . at a trajectory," where "trajectory" is properly interpreted to mean an "allowable fixed angle relative to at least the neutral bending axis of the joint." PO Resp. 18–21, 34–36.

In its Reply, Petitioner contends that Patent Owner's suggestion that trajectory limits the challenged claims to a single, fixed angle is "unsupported by the intrinsic evidence." Reply 4. Specifically, Petitioner contends that

> The claims recite only that the claimed "trajectory" is the transfixation screw trajectory, and that such trajectory is configured to pass through "a first position on the first [discrete] bone[, a portion of the joint,] and a second position on the second [discrete] bone" once the plate is placed across the joint. (EX1001, cls. 1, 11). *There is a wide range of angles at which*

> *this can be achieved, not just one fixed angle*. (EX1001, cl. 4; EX1027, ¶11)).

Reply 2–3 (emphasis added). Petitioner further contends that "the inner surface of the transfixation screw hole does not, alone, determine the precise angle of the trajectory," as "the size, shape, and geometry of the screw also determine what angles the trajectory may have." *Id.* at 3 (citing Ex. 1027 ¶¶ 12–13).

Moreover, Petitioner contends that "Patent Owner's reliance on the 'neutral bending axis' as a point of reference for 'trajectory' is nonsensical" because "the neutral bending axis of a particular joint may shift depending on the position of the bone plate and the loads exerted on that joint" and, thus, "the 'trajectory' cannot be known by analyzing a bone plate or system alone." *Id.* (citing Ex. 2002 ¶ 39).

I begin this analysis by clarifying that I understand Patent Owner's position to be that the "inner surface of the transfixation screw hole" is not a hole configured to allow a screw to be inserted into a bone at a plurality of angles, but that the language of the claim requires the configuration of a trajectory at a particular angle where that angle may be configured within a certain range. PO Resp. 20 (citing Ex. 2002 ¶ 96; Ex. 1001, 6:48–53). Thus, the dispute between the parties is whether a singular "inner surface of the transfixation screw hole" may be configured to operate so as to accommodate a range of angles, for example, in the same manner that Slater's oblique screw portal allows for screws to be inserted at varied angles through the same hole. *Id.*; Ex. 1002 ¶ 121 ("One significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required.") (quoting Ex. 1005, 16:28–30); Ex. 2002 ¶ 103 ("I

agree with Dr. Gall that *Slater* teaches a screw hole that allows a screw to be inserted at a wide range of angles").

With that important distinction in mind, I consider Patent Owner's contention that the term "a trajectory" as used in the challenged claims means an allowable "fixed angle relative to the neutral bending axis of the joint." PO Resp. 18–20, 35–36. Here, I note that the challenged claims themselves define what angles are "allowable." That is, an allowable angle for the transfixation screw is an angle that directs the screw "through a first position on the first discrete bone, a portion of the joint, and a second position on the second discrete bone." Ex. 1001, cl. 1; *see also id.* at cl. 10 ("through a first position on the first bone and a second position on the second bone"); *id.* at cl. 16 ("through a first position on the first bone and a second position on the second bone").

Regarding Patent Owner's inclusion of the phrase "relative to the neutral bending axis of the joint" in its proposed construction of "trajectory," I recognize that the specification makes constant reference to the "neutral bending axis" and its relationship to the trajectory is defined by the disclosed transfixation screw hole. *See e.g.* Ex. 1001, 1:62–63 ("the trajectory may be configured to cross a neutral bending axis of the joint once the plate is placed across the joint"); *id.* at 2:59–63 ("the inner surface of the transfixation screw hole in the plate may direct the transfixation screw along a trajectory that crosses a neutral bending axis of the joint"); *id.* at 6:7–11 ("When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show in FIG. 2), a 'tension band' construct is created that puts transfixation screw 150 under tension when joint 106 flexes."). Furthermore, later dependent claims, when accounting for the precise angles recited by those claims, expressly recite angles

measured from the neutral bending axis of the joint. *See*, *e.g.*, Ex. 1001, cl. 5 ("herein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis."). I also recognize Dr. Gall's and Mr. Sommer's statements explaining that the axis of a bone plate may generally approximate the direction of the neutral bending axis of the joint. Ex. 1002 ¶ 135 ("When a bone has a reasonable degree of symmetry, the axis of the bone plate approximates the direction of the neutral bending axis of the joint."); Ex. 2002 ¶ 95. Given the guidance set forth in the specification, summarized above, and the apparent agreement between the expert testimony, the trajectory of the recited screw could be measured "relative to both the elongate axis of the plate and the neutral bending axis of the joint." PO Resp. 20. Nonetheless, I also note that our express determination of whether a trajectory should be measured from an elongate axis or neutral bending axis of the joint is unnecessary as such a determination would not affect the outcome of our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999))).

The dispositive question is whether the recited transfixation screw hole is configured to direct the transfixation screw on a trajectory that is a fixed angle or is configured to allow for "adjustable orientation" based on "a predetermined allowable angular range" such as opening 26 of Slater, identified by Petitioner as the transfixation screw hole. Pet. 11; Ex. 1005, 12:23–25, 11:21–22. Here, I first note the specification does not describe a plate having a hole identified as a transfixation screw hole that would

accommodate insertion of a screw at a plurality of angles through the same hole. Rather, the specification repeatedly describes the disclosed plate system as having a transfixation screw hole where it is the inner surface of that hole that is configured to direct a screw at a trajectory, which, according to Mr. Sommers, is language a person of ordinary skill in the art would understand to describe a degree of precision around a single fixed angle. Ex. 1001, 1:26–45, 2:8–14, 2:42–46; Ex. 2002 ¶¶ 50, 94, 96; PO Resp. 18–21. For example, the specification describes how "increased plate thickness around transfixation screw hole 102 may also enable transfixation screw hole 102 *to be machined* into bone plate 100 *at an angle* relative to the top surface of bone plate 100." Ex. 1001, 9:8–12 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:60–61; 6:41–67. By comparison, other holes in the disclosed plates are not disclosed with the same level of effort toward precision when describing the trajectory of a screw. Indeed, the specification even includes a description of an oblong opening such as the one found in Slater, described as compression hole 132 and serves the purpose of tightening bones so as to "to press together at the interface of joint 106." *Id.* at 9:12–9:46. Taken together, the specification, when read as a whole, describes plates with a transfixation screw hole configured at a single trajectory selected to achieve the functional objectives of the plate, namely, joint fusion, where that single trajectory is preferably between 30 and 70 degrees, and more preferably, 50 degrees. *Id.* at 6:41–55. Petitioner fails to direct us to any example or other disclosure to support its alternative interpretation, namely, a plate configured with a transfixation screw hole 102 configured to permit the placement of a screw at a plurality of trajectories or angles.

Second, other dependent claims support the interpretation of a trajectory configured at a fixed angle. Claim 2, for example, recites that the "central axis of the inner surface of the transfixation screw hole defines the trajectory," a distinguishing feature as compared to the device in Slater that I will discuss here by way of comparison. Figure 1 of Slater depicts, in phantom, the use of screw 25 that passes through the tibia and terminates in the talus. PO Resp. 10 (citing Ex. 2002 ¶ 55). The hole that screw 25 passes through is oblique[13] and allows the angle of the screw to be modified as the plate is affixed to the ankle joint. *Id.* at 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). In other words, the oblong hole of Slater is specifically designed to not have a central axis that defines the screw trajectory. (Ex. 2002 ¶ 124); *see also* Ex. 2002 ¶ 98 (Figure 1 of Slater "does not detail anything at all regarding the structure of [the 'inner surface' of the transfixation screw hole], much less demonstrate the hole has an 'inner surface configured to direct the transfixation screw . . . at a trajectory.'")

Claim 4 includes an allowable range between 30 and 70 degrees for the trajectory. Claim 4, however, depends from claim 2, and therefore requires the central axis of the screw hole to define the trajectory of the screw between 30 and 70 degrees. Upon review of this claim structure for

[13] It is undisputed that the hole identified by Petitioner as the transfixation screw hole is oblong. As noted by Patent Owner, this hole is described as "slotted," which means "that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles." PO Resp. 11 (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8). Likewise, Dr. Gall recognizes the same hole as the transfixation screw hole of Slater and describes it as an "oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required." Ex. 1002 ¶ 114; Ex. 1005, 16:28–30.

the ’716 patent, I agree with Patent Owner that a person of ordinary skill in the art would understand that, in the context of the intrinsic record, this means that any given plate is configured at a single trajectory or single fixed angle, and that different plates could have a different fixed angle, with plates having single fixed angles in the range between 30 and 70 degrees. PO Resp. 20 (Ex. 2002 ¶ 96; *see also* Ex. 1001, 6:41–55). Here, I also credit Mr. Sommer’s explanation that a person of ordinary skill in the art would understand that to mean that a surgeon would be provided with a kit that includes multiple plates, each one with a single fixed angle of, for example, 50, 55, 60, 65 and 70 degrees. Ex. 2002 ¶ 96; Sur-Reply, 4. Moreover, claim 5 further limits the trajectory of claim 4 to “a transfixation angle of about 50 degrees measured from the neutral bending axis.” Claim 6 further limits claim 1 and requires that “the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw,” and that engagement of the screw head and screw hole would inherently constrain the configuration of the screw hole to a particular angle. Thus, each of dependent claims 2–6 further limit claim 1 along the lines of a single “trajectory” and are more specifically directed to plates configured with a screw hole that defines a single trajectory.

Finally, while the term “trajectory” used in isolation may not necessarily connote a fixed angle, the assessment here is whether the recitation of an inner surface of a screw configured to direct a screw *at a trajectory* is describing a fixed angle, and more specifically, describing a screw hole configured to direct a screw at a single trajectory. In view of the claim structure of independent claims 1, 10, and 16, the content of the specification, and testimony of Mr. Sommer’s, summarized above, I determine it does. The claims expressly require a transfixation screw hole

that itself is "configured to direct the transfixation screw through [a] transfixation screw hole . . . *at a trajectory*," which in context indicates that a screw hole directs the trajectory of the screw, even if other factors may also influence the trajectory. *Cf.* Reply 3–4. In other words, we agree with Patent Owner that "a POSITA reading [claim 1] in light of the intrinsic record would understand that [the claim language describing the recited screw hole] means that the shape of the inner surface of the transfixation screw hole is such that it guides the screw at a fixed angle relative to both the elongate axis of the plate and the neutral bending axis of the joint." PO Resp. 20; Ex. 2002 ¶ 95.

I recognize Petitioner's argument that "[w]hile Slater's transfixation screw hole allows the transfixation screw to be positioned within a predetermined range, once the screw is threaded into the bone, the screw trajectory, and thus the angle, is fixed," however, I am not persuaded. Reply 12. Petitioner insufficiently explains how the fixation of the angle of the screw trajectory by virtue of being inserted into a bone equates to the claim requirement that the inner surface of the transfixation screw hole directs the screw at a trajectory.

Petitioner's challenge to dependent claims 2–5, 9, 11–13, and 17–19 as anticipated by Slater is substantially similar to its analysis of independent claims 1, 10 and 16, which relies on Petitioner's predicate analysis on the independent claims. Pet. 27–32, 36. That analysis suffers from at least the same shortcomings discussed here for independent claims 1, 10 and 16.

In view of the above, I determine that Slater does not disclose "the transfixation screw hole comprising an inner surface configured to direct [a] transfixation screw . . . at a trajectory" as required by the claims. Slater's opening 26 is meant to be a variable angle hole and not an opening

configured to direct a screw at a particular angle or trajectory. *See* Ex. 1005, 11:19–22 ("an angle within a predetermined allowable angular range"); *see also* Ex. 2003, 65:1–4 (Dr. Gall agreeing that each of the angles depicted by phantom screws shown in Figure 1 of Slater are achieved through the same screw hole 26). Accordingly, for this additional reason, I determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–5, 9–13, and 16–19 are anticipated by Slater.

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Paper 46
Date: March 15, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01453
Patent 10,245,085 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges.*

Opinion by the Board filed by *Administrative Patent Judge* MARSCHALL.

Opinion dissenting-in-part filed by *Administrative Patent Judge* SNEDDEN.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") challenges claims 1–9 of U.S. Patent No. 10,245,085 B2 ("the '085 patent," Ex. 1001), which is assigned to Patent Owner OsteoMed LLC. We have jurisdiction under 35 U.S.C. § 6, and we issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 (2019). For the reasons set forth below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–7 of the '085 patent are unpatentable and that Petitioner has not shown by a preponderance of the evidence that claims 8 and 9 are unpatentable.

BACKGROUND

A. *Procedural History*

Petitioner filed a Petition requesting *inter partes* review of the challenged claims. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response. Paper 5. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of claims 1–9 of the '085 patent on all presented challenges. Paper 6 ("Inst. Dec.").

After institution, Patent Owner filed a Response (Paper 23, "PO Resp."), Petitioner filed a Reply (Paper 27, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 33, "PO Sur-reply"). An oral hearing in this proceeding was held on December 15, 2022, and a transcript of the hearing is included in the record (Paper 42, "Tr.").

B. *Related Matters*

Petitioner filed related petitions for *inter partes* review in IPR2021-01450, IPR2021-01451, and IPR2021-01452 for related U.S. Patent Nos. 8,529,608; 9,351,776; and 9,763,716, respectively. Pet. 1–2; Paper 3, 1–2. Patent Owner also identifies the following related matters involving the

same patents, but not the ’085 patent: IPR2022-00189, IPR2022-00190, and IPR2022-00191. Paper 15, 2. The parties indicate that Patent Owner asserts the ’085 patent against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.) and in *OsteoMed LLC v. Wright Medical Technology, Inc.*, Case No. 1:20-cv-1621 (D. Del.). Pet. 1–2; Paper 3, 1–2.

C. The ’085 patent

The ’085 patent discloses a “system for securing bones together across a joint.” Ex. 1001, code (57) (Abstract). The system may be used for reconstructing a joint that has been damaged due to bone or soft tissue trauma, in which a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint. *Id.* at 1:28–32.

The ’085 patent discloses that its system has “the ability to tightly couple the bones of a joint together” by including a transfixation screw inserted across the joint through a bone plate. *Id.* at 2:44–46. More specifically, the ’085 patent discloses that the presence of the transfixation screw across the joint “may increase the contact pressure on the bony interface of the joint, increasing the probability of a positive fusion.” *Id.* at 2:57–62. According to the ’085 patent, by having the transfixation screw passing from the first bone to the second bone, a “tension band” construct is created “that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint,” thereby enhancing the integrity and reliability of the plate and increasing the load that the plate may support without increasing plate thickness. *Id.* at 2:67–3:7.

Figure 2, reproduced below, shows "a bone plate being used in conjunction with a transfixation screw to repair the failed metatarso-phalangeal joint" and immediately below it is Figure 3, which shows "a more detailed isometric view of the bone plate." *Id.* at 3:22–27.

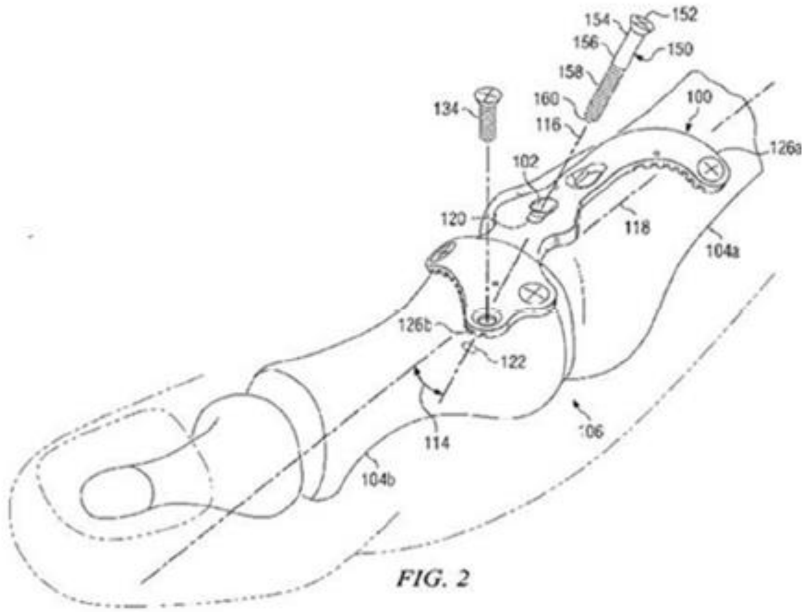


FIG. 2

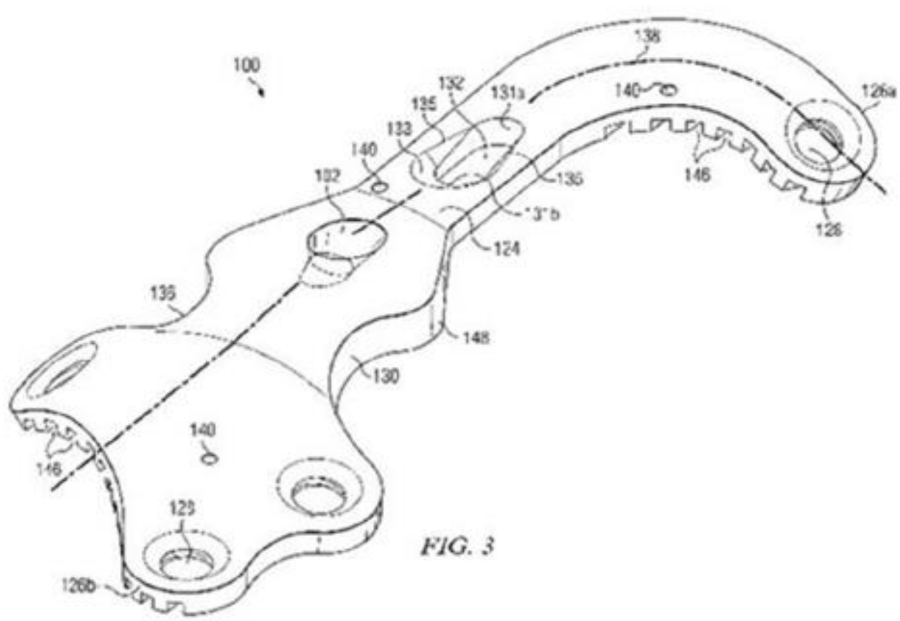


FIG. 3

Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id.* at 4:29–31. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b "in order to fuse joint 106." *Id.* at 4:42–47. Figure 3 shows bone plate 100 having elongated spine 124 and bridge portion 130 between first end 126a and second end 126b that can span across joint 106. *Id.* at 7:45–54. First end 126a includes attachment point 128 "for attaching first end 126a to bone 104a" and second end 126b includes another attachment point 128 "for attaching second end 126b to bone 104b." *Id.* The '085 patent discloses that bridge portion 130 "is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130" and may include thickened section 136 of bone plate 100 "to increase the bending strength of bridge portion 130." *Id.* at 8:41–39.

D. Challenged Claims

The '085 patent includes nine claims, all of which are challenged, with claim 1 the only independent claim. We reproduce claim 1 below.

> 1. A system for securing a first discrete bone and a second discrete bone together across a joint between the first discrete bone and the second discrete bone, the system comprising:
>
> a plate comprising:
>
> an elongate spine having a first end comprising at least one attachment point for attaching the first end to the first discrete bone on a first side of the joint, a second end comprising at least one attachment point for attaching the second end to the second discrete bone on a second side of the joint, and a bridge portion disposed between the first end and the second end, the bridge portion having a portion configured to span across the joint, the bridge portion further comprising a thickened portion

having a thickness greater than at least a portion of a thickness of either the first end or the second end; and

an aperture defining a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends at a trajectory configured to pass through a first position on the first discrete bone and a second position on the second discrete bone once the plate is placed across the joint.

Ex. 1001, 12:28–53.

E. Asserted Ground of Unpatentability

Petitioner asserts that claims 1–9 are unpatentable based on the following grounds (Pet. 4):

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1–3, 6–9	102(b)[1]	Slater[2]
4, 5	103(a)	Slater, Weaver[3]
1–8	102(b)	Falkner[4]
9	103(a)	Falkner, Arnould[5]
1–3, 6–9	103(a)	Arnould, Slater
4, 5	103(a)	Arnould, Slater, Weaver

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Based on the putative effective filing date of the '085 patent, we apply the pre-AIA versions of §§ 102 and 103.

[2] Slater, WO 2007/131287 A1, published Nov. 22, 2007 (Ex. 1005, "Slater").

[3] Weaver et al., US 6,623,486 B1, issued Sept. 23, 2003 (Ex. 1009, "Weaver").

[4] Falkner, US 2005/0171544 A1, published Aug. 4, 2005 (Ex. 1006, "Falkner").

[5] Arnould, EP 1 897 509 B1, published Mar. 12, 2008 (Ex. 1007). Petitioner states that Exhibit 1008 is a certified English translation of Exhibit 1007 (Pet. 4) and we refer to Exhibit 1008 as "Arnould."

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1027) and Dr. George B. Holmes, Jr. (Ex. 1028) to support its contentions. Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

ANALYSIS

A. Legal Standards

To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e) (2012); 37 C.F.R. § 42.1(d) (2018). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner.[6] *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burdens of proof in an *inter partes* review).

Petitioner relies on both anticipation and obviousness in its challenges. To anticipate a claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That "single reference must describe the claimed invention with sufficient

[6] Although we primarily address Patent Owner's arguments below and identify many of them as unpersuasive, we do not shift the ultimate burden from Petitioner. We focus on such arguments because they identify issues in dispute and we address them as unpersuasive only in the context of the record and Petitioner's assertions.

precision and detail to establish that the subject matter existed in the prior art." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

A claim is unpatentable as obvious under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) where in evidence, so-called secondary considerations, also known as objective indicia of non-obviousness.[7] *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). "The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art" at the time of the invention. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational

[7] The parties do not introduce any evidence pertaining to objective indicia of nonobviousness.

level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.*

Petitioner asserts that one of ordinary skill in the art would have "at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon." Pet. 10 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner's proposal. *See* PO Resp. 20.

We adopt Petitioner's asserted level of ordinary skill because it is consistent with the problems identified and solutions provided in the '085 patent and the prior art.

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner takes the position that "[t]here are no claim terms in the Challenged Claims that require construction" and that Petitioner has "applied the ordinary and customary meaning of each claim term." Pet. 10–11 (*citing Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)). Patent Owner generally agrees that the claim terms should be given their ordinary and customary meaning, and also argues that we should find the preamble of claim 1 limiting. PO Resp. 16–17.

Having considered the parties' positions and evidence of record, we determine that we need not expressly construe any claim term to resolve any of the challenges we consider in this Decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

D. Summary of Cited Prior Art

1. Summary of Slater

Slater relates to an ankle fusion plate for fusion of the anterior ankle. Ex. 1005, 1:6–7. Slater discloses that orthopedic devices can repair diseased bones and bone fractures. *Id.* at 1:21–22. Slater explains that bones that have been fractured must be kept together for lengthy periods of time to permit recalcification and bonding. *Id.* at 3:1–3. According to Slater, internal fixation techniques require "the fracture be stable axially, torsionally and rotationally." *Id.* at 3:19–25; 7:1–2. To achieve such objectives, Slater discloses a fixation screw and plate design in which "the plate depth changes at different locations" so that "the depth at the beginning a[n]d end points of the L shaped contour [of the plate] over the ankle joint in the second region will be at it[s] maximum thickness." *Id.* at 8:27–34. Slater further discloses that "[t]he plate will taper at least one but preferably two different points of the plate" and that "[t]hese points will preferably resemble and conform to the typical geometry of the anatomical region." *Id.* at 9:3–4, 11–12.

Figure 1, reproduced below, shows a side elevation view of a plate attached via fixation screws "to an abbreviated ankle joint (dotted lines)." *Id.* at 9:28–30.

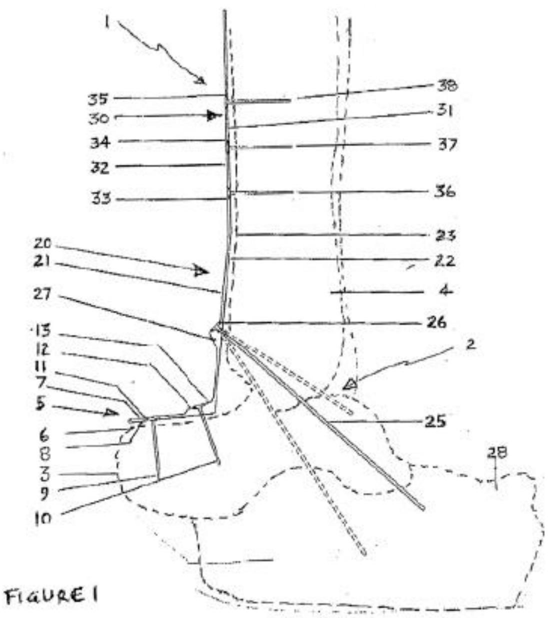


FIGURE 1

Figure 1 shows fusion plate 1 attached to the talus bone 3 and the tibial bone 4 that form ankle joint 2. Ex. 1005, 11:1–4. Fusion plate 1 includes portion 5 "disposed in a first plane which generally aligns with" anterior surface 6 of the talus bone 3 for fixation thereto. *Id.* at 11:5–8. Disposed in portion 5 are fixation screws 9 and 10 which pass through openings 11 and 12 of portion 5 to engage the talus bone 3. *Id.* at 11:8–9. Portion 20 of fusion plate 1 has formation 27 with opening 26 disposed therein for allowing fixation screw 25 to pass therethrough. *Id.* at 11:18–21. "Formation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range" such that fixation screw 25 engages the tibia bone 4, the talus bone 3, and the calcaneus bone 28. *Id.* at 11:21–24. Portion 30 of fusion plate 1 includes openings 33, 34, and 35

which receive fastening screws 36, 37, and 38 to engage tibia bone 4. *Id*. at 11:27–31.

2. Summary of Falkner

Falkner relates to systems for fixing bones using bone plates having apertures for retaining fasteners. Ex. 1006, Abstract. Falkner discloses that fixation of bone fractures can be problematic when these fractures are disposed near the ends of bones. *Id*. ¶ 4. Falkner purports to resolve past problems of achieving an interference fit that is tight enough to prevent slippage of a blade portion of the bone plate relative to an interlocking bone screw. *Id.* ¶ 6.

Figure 1, reproduced below, shows a sectional view of a system for fixing bones using a bone plate with a toothed aperture such that the bone plate is secured to a fractured bone. *Id.* ¶ 8.

Fig. 1

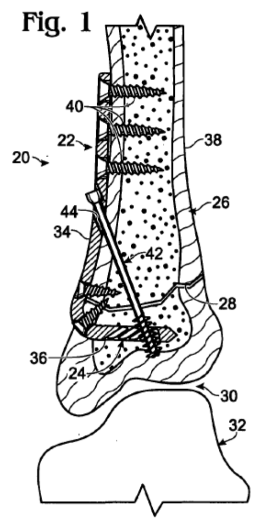


Figure 1 shows system 10 including bone plate 22 with toothed aperture 24 in which bone plate 22 "may be positioned on and/or in any suitable bone(s) to span . . . within a bone or between bones" such as on a region of the tibia bone 26 that spans fracture 28, as depicted. Ex. 1006 ¶ 21. Thus, bone plate 22 may span joint 30 between tibia bone 26 and talus

bone 32. *Id*. Bone plate 22 includes first plate portion 34 and second plate portion 36. *Id.* ¶ 22. Falkner discloses that bone screws 40 "may be placed into bone from any suitable number of openings of the bone plate." *Id.* ¶ 23. Threaded fastener 42 may extend through opening 44 and toothed aperture 42 of bone plate 22. *Id.* ¶ 24. Falkner discloses that bone plate 22 "may be sized and shaped to conform to particular portions of a bone (or bones)" and "may be thicker and thus stronger in regions where they may not need to be contoured, such as along the shaft of the bone." *Id.* ¶¶ 33, 35. Thickness of bone plate 22 "may be varied" within and a thicker portion may be provided to "increase structural stability." *Id.* ¶ 35.

3. Summary of Arnould

Arnould "relates to an arthrodesis plate for a metatarsal-phalangeal joint." Ex. 1008 ¶ 1. Arnould discloses that a leg of its plate "allows the plate to be attached to a lateral surface of the epiphysis of the phalanx." *Id.* ¶ 6. Arnould explains that "this leg is shaped so that its end hole can receive a long screw . . . which will extend both through the bone material of the phalanx and into the bone material of the metatarsal." *Id*. Thus, the "long screw extends lengthwise in a direction having an anteroposterior component, so that this screw essentially, if not exclusively, takes up the bending stresses generated during the patient's walking." *Id*.

Figure 1, reproduced below, shows a perspective view of an arthrodesis plate "placed and fixed on a metatarsal-phalangeal joint locked by the plate." *Id*. ¶ 10.

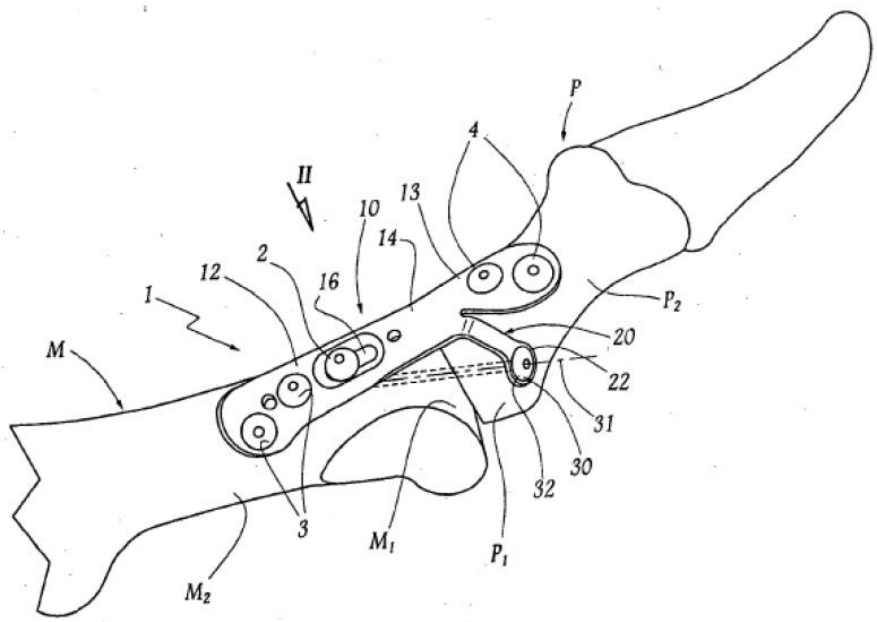


Fig. 1

Figure 1 shows arthrodesis plate 1 on a joint between metatarsal M and first phalanx P of a toe. *Id.* ¶ 11. Plate 1 includes plate body 10 and leg 20. *Id.* ¶ 13. Screws 3 and 4 secure opposite ends of plate body 10 to the bones as shown. *Id.* ¶¶ 33–34.

Leg 20 includes a through-hole for receiving screw 30 that has sufficient length to extend from the through-hole "into both the phalangeal epiphysis P_1 and the metatarsal epiphysis M_1, and possibly also into the metatarsal diaphysis M_2." Ex. 1008 ¶ 26. Arnould states that "the leg 20 is bent downward relative to the plate body 10 along a bend line 23 substantially perpendicular to the longitudinal direction 21 and located at the junction between the leg and the phalangeal portion 13." *Id.* ¶ 24. Between the metatarsal portion 12 and phalangeal portion 13, there is a "zone 14" described as a "joint zone" or "junction zone." *Id.* ¶¶ 14–15. Arnould discloses that it is advantageous to include a junction zone with a "bending

line 141" to allow "better adaptation of the plate body 10 to the anatomy of the . . . joint when it is locked." *Id.* ¶ 20.

4. Summary of Weaver

Weaver is directed to a bone plating system for fracture fixation, which includes a bone plate having plate holes for both locking and non-locking screws. Ex. 1009, 1:10–13. Weaver discloses that "[s]ecuring the screws to the plate provides a fixed angle relationship between the plate and screw and reduces the incidence of loosening" and such screws are called "locking screws." *Id.* at 1:46–49. According to Weaver, a known locking screw has threading on an outer surface of its head that mates with corresponding threading on the surface of a plate hole to lock the screw to the plate. *Id.* at 1:49–54. Weaver discloses that "locking screws provide a high resistance to shear or torsional forces." *Id.* at 1:56–58. However, existing bone plating systems under high stress and loading conditions may have a locking plate hole that is distorted and allows the fixed angular relationship between the locking screw and plate to change. *Id.* at 2:20–22. Weaver purports to resolve such deficiencies in its bone plating system. *Id.* at 2:28–29.

Figure 3, reproduced below, shows a side view of an exemplary bone plate. *Id.* at 3:25.

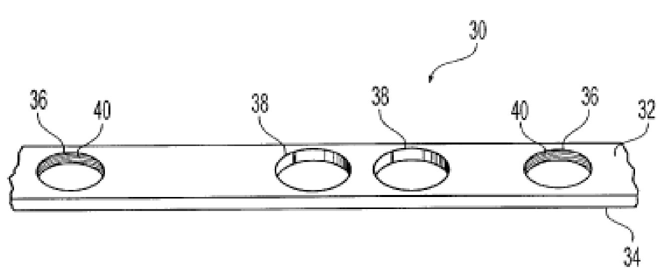


Fig. 3

Figure 3 shows bone plate 30 including first plate holes 36 and second plate holes 38. Ex. 1009, 4:45–46. Each first plate hole 36 has thread 40 that mates with thread 24 on head 22 of locking screw 20 (shown in Figure 2) to secure locking screw 20 to bone plate 30 at a temporally fixed angular orientation whereas second plate holes 38 are not threaded and receive non-locking screws 10 with non-threaded heads 12 (shown in Figure 1). *Id.* at 4:47–53. Weaver discloses that "[f]irst plate holes 36 are preferably conical in shape" and that "threads 40 on first plate holes 36 are also preferably double lead threads" which enable engagement "while maintaining a low profile." *Id.* at 5:1–5.

E. Anticipation of Claims 1–3 and 6–9 by Slater

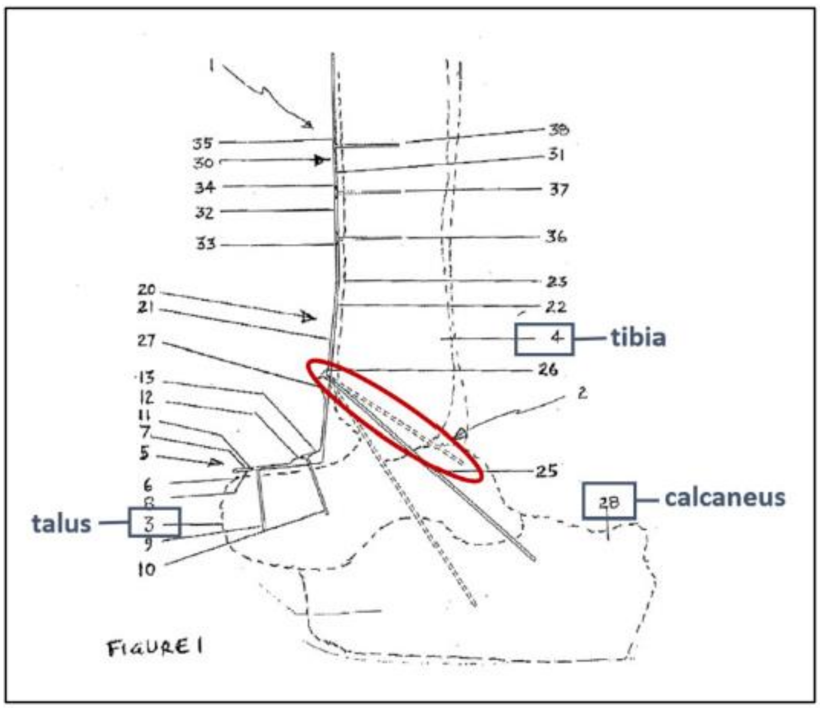
Petitioner contends that Slater discloses all elements of claims 1–3 and 6–9, and thus anticipates those claims under 35 U.S.C. § 102(b). Pet. 17. To support its contentions, Petitioner directs our attention to the discourses of Slater and provides a detailed claim analysis addressing how Slater discloses each element of claims 1–3 and 6–9. Pet. 17–34 (citing Ex. 1002). Patent Owner argues that (1) Petitioner improperly relies on multiple, discrete embodiments in Slater; (2) Slater fails to disclose the preamble of claim 1; (3) Slater fails to disclose "the bridge portion further comprising a thickened portion"; and (4) Slater fails to disclose "a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion." PO Resp. 21–32.

Having considered the parties' positions and evidence of record, we determine that Petitioner has demonstrated by a preponderance of evidence that claims 1–3, 6, and 7 are anticipated by Slater and has not demonstrated that claims 8 and 9 are anticipated by Slater. Our analysis follows.

1. Claim 1

a. The Preamble and the Multiple Embodiments Dispute

The preamble of claim 1 requires a "system for securing a first discrete bone and a second discrete bone together across a joint between the first discrete bone and the second discrete bone." Petitioner contends that, if the preamble limits claim 1, Slater discloses a system for securing two discrete bones together across a joint between the two bones. Pet. 17–18.[8] In support, Petitioner directs our attention to its annotated Figure 1 of Slater, reproduced below, which shows "a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines)." Pet. 18; Ex. 1005, 9:28–30.



[8] We need not decide whether the preamble limits the claim because Slater discloses a system for securing two bones as the preamble requires. Moreover, although other portions of claim 1 might limit it to a system for securing two (and only two) bones, the preamble (if limiting) does not appear to exclude a system that secures more than two bones.

Id. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* With reference to the figure above, Petitioner asserts that

> Figure 1 of Slater illustrates (1) a fusion plate 1 being used to secure three discrete bones (tibia 4, talus 3, and [calcaneus] 28) across two joints and (2) an alternate embodiment where fusion plate 1 is used to secure two discrete bones (tibia 4 and talus 2, within the oval annotated into Figure 1 [above]) together across a single joint between the two bones.

Pet. 18 (citing Ex. 1002 ¶ 133; Ex. 1005, 12:3–4, 6:17–7:2, 8:13–28, 11:1–4, 12:3–10, 13:5–9, 14:1–8). Petitioner supports this interpretation of Slater with Dr. Gall's testimony. *See* Ex. 1002 ¶ 133.

Patent Owner contends that Petitioner relies "on different embodiments described throughout the disclosure, including the distinct two- and three-bone embodiments detailed in Figure 1, as well as various other plates disclosed in Slater, such as the Figure 5 plate." PO Resp. 22 (citing Ex. 2002 ¶ 58). As to Figure 1, Patent Owner contends that the specification focuses on the three-bone embodiment and Petitioner improperly relies "on expert testimony to fill the gaps regarding how the three-bone embodiment would be modified for a two-bone application." *Id.* at 23 (citing Pet. 2, 18–34; Ex. 1005, 14:1–3; Ex. 2002 ¶¶ 75–84). Patent Owner also argues that Petitioner relies on multiple embodiments, including aspects of Figure 5, to meet the "bridge portion further comprising a thickened portion" limitation, which lacks support in Slater given that there are several differences between Figures 1 and 5, such that viewing them as describing the same embodiment, as Petitioner and Dr. Sommers do, lacks support. *Id.* at 24 (citing Ex. 1005, Figs. 1, 5, 6 (annotated); Ex. 2002 ¶ 58;

Ex. 2003, 72:20–73:7). Turning to the preamble, Patent Owner argues that Petitioner relies "on Slater's disclosure of a dotted line two-bone screw in Figure 1 in combination with Slater's disclosure of a plate used with a screw across three bones." *Id.* at 26. Patent Owner also contends that "the conclusory nature" of Dr. Gall's declaration highlights the lack of disclosure in Slater as to the two-bone embodiment. *Id.* at 27 (citing Ex. 1002 ¶ 133; Ex. 1005, 12:3–4, 8:27–28, 14:1–2). According to Patent Owner, Slater primarily focuses on its three-bone embodiment and fails to describe the two-bone embodiment or the use of screw 25 with the two-bone embodiment. *Id.* at 27–28 (citing Ex. 1005, 16:28–30; Ex. 2002 ¶¶ 75–84).

In its Reply, Petitioner argues that "Slater is replete with references indicating that ***the same plate*** may be used to fuse two bones or three bones. Pet. Reply 3 (citing Ex. 1005, 6:18–28, 8:27–28, 12:3–5, 14:1–3, 16:28–32,17:3–5). Petitioner also argues that Patent Owner adopts Petitioner's approach, that Slater's Figure 1 discloses a screw and plate that work with a two-bone embodiment and reliance on Figures 1 and 5, in related *inter partes* reviews. *See id.* (citing Ex. 1025 ¶ 81; Ex. 1026 ¶ 76), *id.* at n.1 (citing IPR2022-00487, Pet., 21–25; IPR2022-00488, Pet., 18–19). Petitioner contends that Figures 1 and 5 disclose the same embodiment for purposes of anticipation because Slater describes Figure 1 as a "generally schematic view of a fusion plate 1" attached to an ankle joint and Figure 5 "shows a side cross sectional elevation view of a plate according to a preferred embodiment isolated from an ankle joint." *Id.* at 3–4 (citing Ex. 1005, 10:6–7, 11:1–4). Petitioner also contends that "[t]he detailed description of Figure 5 refers back to plate 1 of Figure 1 and the screw orientations disclosed therein, thus clarifying that the figures disclose

different aspects of the same preferred embodiment." *Id.* at 4–5 (citing Ex. 1005, 9:21–10:27, 10:32, 13:5–6, 14:1–2; Ex. 2003, 72:20–73:7). According to Petitioner, any differences between Figures 1 and 5 "are largely due to the fact that Figure 1 is a schematic drawing intended to illustrate the positioning of the bone plate and screws relative to the joint, whereas Figure 5 is a cross-sectional drawing intended to illustrate additional details regarding the width and thickness of the bone plate and the geometry of the openings." *Id.* at 5 (citing Ex. 1005, 11:1–12:10, 13:5–14:10) (emphasis removed). Petitioner also reiterates its argument that Slater discloses a two-bone embodiment as the preamble requires, as well as a screw for use in that approach. *Id.* at 7–9.

In its Sur-reply, Patent Owner argues that "the Figure 5 plate 80 embodiment is unique in numerous ways that make clear that it is not the same as the Figure 1 plate 1 embodiment" and that the "structural differences between the two plates are not explained by the 'schematic' nature of Figure 1." PO Sur-reply 7–9 (citing Ex. 2002 ¶ 58; Ex. 1005, Figs. 1, 5–7). Patent Owner also argues that Slater fails to support Petitioner's argument that Slater treats all of the disclosure as a single embodiment. *Id.* at 9–10.

We first address whether Petitioner improperly relies on multiple embodiments within Figure 1 itself when it relies on the dotted lines showing a screw located within two, but not three, bones. *See* Pet. 18. Petitioner may not, to support its anticipation challenge, pick and choose from "various disclosures *not directly related to each other* by the teachings of the cited reference." *In re Arkley*, 455 F.2d 586, 587 (1972) (emphasis added). But here, the disclosures of Slater relied upon by Petitioner are

sufficiently related to each other as evidenced by at least Figure 1 itself, and the related written description in Slater. The two-bone embodiment appears to be an "alternate" embodiment only insofar as it reflects another angled pathway for the screw so it anchors in a second and not a third bone. This is not wholly distinct, however, from the three-bone embodiment because both the two-bone and three-bone embodiments are depicted as alternatives within the plate of Figure 1 itself. Figure 1 shows a plate on an ankle, with three potential alternative screw locations—two contacting three bones and a third screw orientation contacting two bones. *See* Ex. 1001, Fig. 1; Pet. 18. Although the three disclosed screw orientations can be thought of as three different approaches and therefore three different embodiments in some sense, we do not see any issue with Petitioner's reliance on one of those screw orientations with the disclosed plate as problematic. *See* Pet. 18. Petitioner does not pick and chose from multiple potential "embodiments" within Figure 1 and instead relies only on the screw shown in contact with two bones. *See id.* For example, Petitioner does not rely on two different screw orientations as part of its anticipation argument. *See id.*

We also do not view Petitioner's reliance on Slater's text as improperly relying on multiple embodiments. Patent Owner seems to take the position that the specification only refers to the three-bone embodiment because it does not explicitly refer to the two-bone embodiment, but Figure 1 makes clear that the disclosed plate and screw can be used with any of the disclosed screw orientations, such that any discussion of that plate should be read as part of the two-bone embodiment Petitioner relies on as well as the three-bone embodiment. *See* Ex. 1001, Fig. 1; PO Resp. 23. Accordingly, Patent Owner's argument that Petitioner fails to explain how to

modify these disclosures to arrive at the two-bone embodiment misses the mark. *See* PO Resp. 23.

With that background, we turn to Petitioner's contention that Slater discloses the preamble. *See* Pet. 17–18. Petitioner argues that Slater discloses a "system for securing a first discrete bone and a second discrete bone together across a joint between the first discrete bone and the second discrete bone" as required by the preamble. *See id.* We agree. As noted above, Slater's Figure 1 shows a plate across an ankle joint that secures a first bone and second bone. *See id.*; Ex. 1002 ¶ 133; Ex. 1005, Fig. 1, 8:27–28, 9:28–30, 12:3–4, 14:1–2.

Patent Owner's arguments as to the preamble largely hinge on its argument that Petitioner improperly relies on multiple embodiments or that Slater fails to describe a two-bone embodiment, two arguments we find unpersuasive for the reasons provided above. *See* PO Resp. 26–28. Patent Owner argues that Slater primarily focuses on its three-bone embodiment, but even disfavored embodiments may still anticipate a claim. *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) ("A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it."). Patent Owner also describes Dr. Gall's testimony as too "conclusory," but we disagree. *See id.* at 27–28. Dr. Gall opines that "Slater also contemplates that the fusion plate 1 can be used to secure two discrete bones (tibia 4 and talus 2, . . .) together across a single joint between the first discrete bone and the second discrete bone" and Slater's Figure 1 supports this testimony by showing a screw path that secures two bones together. Ex. 1002 ¶ 133; Ex. 1005, Fig. 1. Dr. Gall also supports his opinions with citations to Slater that generally support his

opinion that Slater contemplates the use of its plate across a single joint, which involves two bones rather than three bones. *See id.* We view Dr. Gall's testimony as sufficient to support Petitioner's argument, and more credible than the competing testimony Patent Owner relies on. *See* PO Resp. 27–28 (citing Ex. 2002 ¶¶ 75–84).

Patent Owner also argues that Petitioner improperly relies on multiple embodiments when it refers to Figures 1, 5, and 7 when arguing that Slater discloses a bridge portion that includes a thickened portion. *See* PO Resp. 23 (citing Pet. 21–22). This aspect of Patent Owner's arguments does not impact the preamble, which does not refer to the bridge portion or a thickened portion. In addition, as we note below when addressing those limitations, we find that Slater discloses the "bridge portion further comprising a thickened portion" limitation even if we only consider Slater's Figure 1 and the accompanying text. We, therefore, need not reach whether Petitioner's reliance on figures other than Figure 1 amounts to improper reliance on multiple embodiments as part of its anticipation challenge to claim 1.

Based on the foregoing, we find that Petitioner establishes by a preponderance of the evidence that Slater discloses the elements of the preamble to claim 1.

b. Bridge Portion Comprising a Thickened Portion

Claim 1 further requires "the bridge portion further comprising a thickened portion having a thickness greater than at least a portion of a thickness of either the first end or the second end." Petitioner argues that Slater's Figures 5 and 7 show its bridge portion includes a "thickened portion (portions of 5 and 20 or portions of 81 and 90) having a thickness

greater than at least a portion of a thickness of either the first end (proximal end of portion 30 or portion 95) or the second end (distal end of portion 5 or portion 81).” Pet. 22–23 (citing Ex. 1002 ¶ 140, Figs. 5, 7). Petitioner also argues that Slater’s text “discloses that the portion of the plate adjacent the ankle joint will preferably be the thickest part of the plate, while the portions towards the ends of the plate may be thinner.” *Id.* at 23 (citing Ex. 1005, 8:25–26, 8:32–9:6); *see also id.* (“Slater recognizes that the plate should be at its ‘maximum thickness’ at the ‘region that the highest loading will occur in normal use.’” (citing Ex. 1005, 14:19–23)). Petitioner also relies on dependent claim 29, which recites a kit “wherein the plate thickness varies at different locations and wherein the portion of the plate which lays over the ankle joint has maximum thickness.” *Id.* (quoting Ex. 1005, 34:17–19).

Patent Owner argues that Slater’s Figure 1 does not depict the claimed bridge with a “thickened portion” and “Slater describes that this portion of the plate is purposefully designed to be thinner to increase ‘pliability at regions when bending may be required for conformity with bone anatomy.’” PO Resp. 29 (citing Ex. 1005, 17:2–3; Ex. 2002 ¶ 87). Patent Owner also contends that Petitioner improperly relies on a combination of Figure 1 with Figure 5 to meet the limitation, the argument we noted above in the context of Patent Owner’s argument that Petitioner improperly relies on multiple embodiments in its anticipation analysis. *See id.* at 28–30.

In its Reply, Petitioner argues that “Patent Owner wholly fails to address Slater’s specification, which unambiguously teaches and claims that the portion of the plate over the ankle joint will preferably be the thickest part of the plate.” Pet. Reply 10 (citing Ex. 1005, 24:17–19, 8:25–9:6; Ex. 1027, ¶¶ 18, 20–23). Petitioner also contends that “Patent Owner

incorrectly argues that Slater's bridge portion 'is purposely designed to be thinner to increase 'pliability''' because Slater's pliable regions are at its ends where the plate tapers and conforms to the bones—not the bridge portion." *Id.* at 10–11 (citing PO Resp. 29; Ex. 1005, 9:3–12, 14:18–33; Ex. 1027 ¶¶ 20–23). Petitioner also points to the specific dimensions Slater describes to support its argument—"Slater describes the 'maximum thickness' of the plate at the bridge portion over the ankle joint as being 'within the range of 4-8mm,' while the thickness of the plate at the proximal and distal ends is 'around 1mm.'" *Id.* at 11 (citing Ex. 1005, 8:35–9:11, 14:18–30).

Based on our review of the arguments and evidence, Petitioner establishes that Slater discloses a "bridge portion further comprising a thickened portion" as claim 1 requires. Pet. 22–23; Pet. Reply 10–11. We agree with Petitioner that Slater's Figure 5 discloses a thickened bridge portion, but we need not rely on Figure 5—and address Patent Owner's related argument that by doing so Petitioner improperly relies on multiple embodiments—because Slater's text amply supports its position. As Petitioner points out in the Petition and its Reply, Slater repeatedly describes its bridge portion as thicker than both of its ends, claims this aspect of its plate in dependent claim 29, and even provides specific dimensions consistent with its description of a thickened bridge portion thicker than the ends of the plate. Ex. 1027 ¶¶ 20–23; Ex. 1005, 8:25–26, 8:32–9:11, 9:3–12, 14:18–33, 34:17–19. Petitioner also supports these positions with credible expert testimony from Dr. Gall citing to Slater. *See* Ex. 1002 ¶ 140; Ex. 1027 ¶¶ 20–23. Patent Owner fails to acknowledge or address with

credible counterargument any of these portions of Slater that support Petitioner's position. *See* PO Resp. 28–30.

Based on the foregoing, we find that Petitioner establishes by a preponderance of the evidence that Slater discloses "the bridge portion further comprising a thickened portion having a thickness greater than at least a portion of a thickness of either the first end or the second end."

c. Hole Disposed Along the Spine at the Thickened Portion

Claim 1 further requires "a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion." Petitioner argues that "Slater includes an aperture defining a transfixation screw hole (opening 26 or 93) disposed along the spine at the thickened portion of the bridge portion." Pet. 24–25 (citing Ex. 1002 ¶¶ 140–142; Ex. 1005, 11:19–25, 13:21–25, Figs. 1, 5, 7). Petitioner provides annotated versions of Slater's Figures 1 and 7, reproduced below, to illustrate its position.

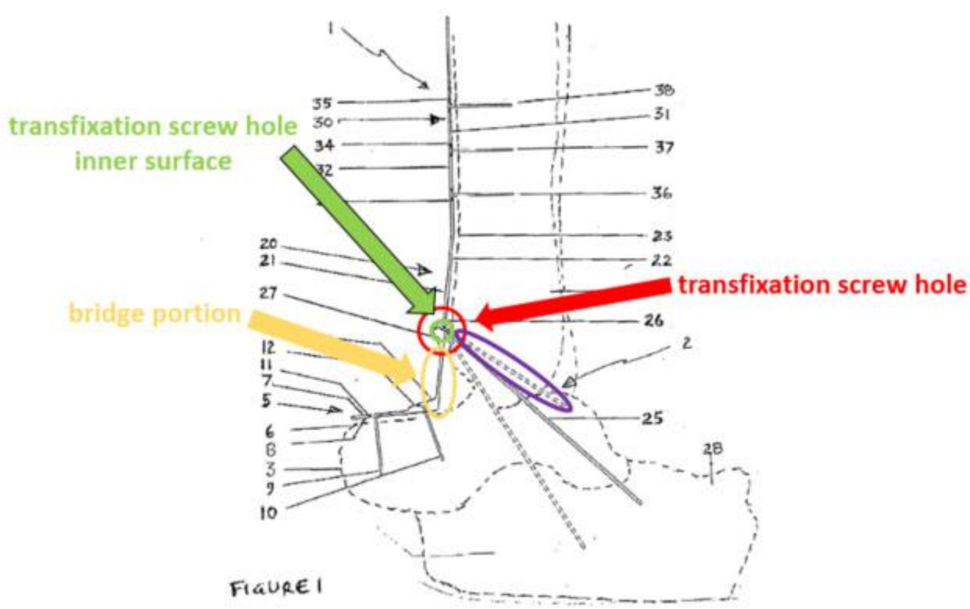


FIGURE 1

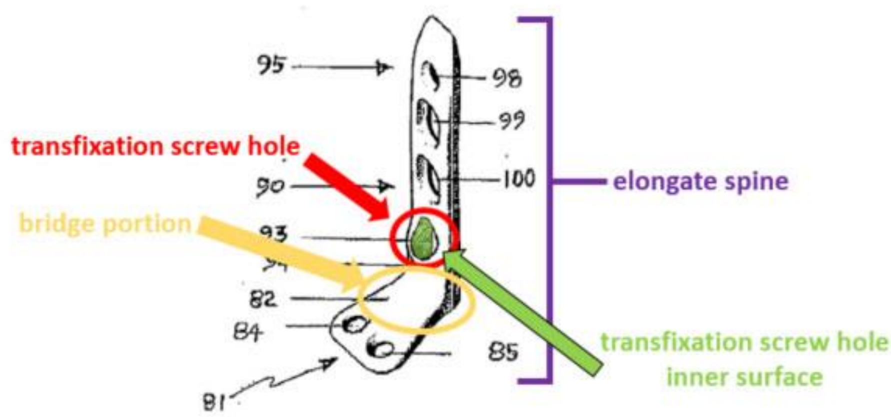


FIGURE 7

The top figure shows an annotated version of Figure 1 while the bottom figure shows an annotated version of Figure 7. *See* Pet. 25. Both figures identify a "bridge portion" in yellow lettering, with a yellow arrow pointing to an oval encompassing a portion of Slater's plate. *Id.* Both figures also identify a "transfixation screw hole" in red with a red arrow pointing to an oval encompassing a hole (26 in Figure 1 and 93 in Figure 7). *Id.* The hole appears adjacent to and directly above the bridge portion in Petitioner's annotated figures. *Id.*

Patent Owner first argues that "neither the Petition nor Dr. Gall's supporting declaration provide any analysis of this claim element other than to simply say it is disclosed in Slater." PO Resp. 30 (citing Pet. 22–23; Ex. 1002 ¶ 140).[9] Patent Owner also contends that the Petition

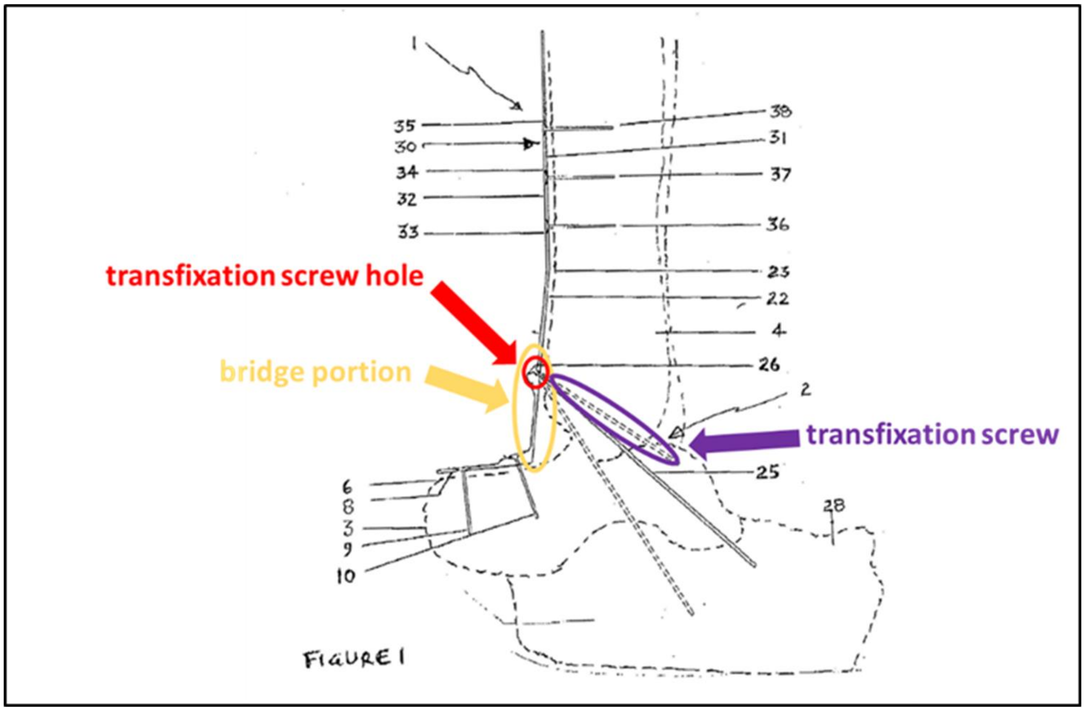
[9] Patent Owner's argument improperly cites to the Petition at pages 22–23 and paragraph 140 of Dr. Gall's declaration as allegedly lacking the requisite analysis, but Petitioner and Dr. Gall do not address this limitation at those passages. *Compare* Pet. 22–23; Ex. 1002 ¶ 140, *with* Pet. ix (annotated version of claim 1), 24–25 (addressing limitation 1.5, which includes the "a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion" limitation) (relying on paragraphs

and Dr. Gall's testimony confirm that Slater does not disclose the limitation because both identify the transfixation screw hole *above* the bridge portion rather than *at* the bridge portion. *Id.* at 30–32 (citing Ex. 1002 ¶ 141; Ex. 2002 ¶¶ 92–94).

In its Reply, Petitioner argues that Patent Owner takes "an overly narrow view of the claim term 'at,'" because "the ordinary meaning of the term 'at' is 'in, on, or ***near***,'" such that "at the thickened portion of the bridge portion" means "***near*** the thickened portion of the bridge portion." Pet. Reply 11 (citing PO Resp. 30–32; Ex. 1031, 77). According to Petitioner, Dr. Gall correctly identifies "Slater's transfixation screw hole as being adjacent to the bridge portion." *Id.* at 11–12 (citing Pet. 24; Ex. 1002 ¶ 141; Ex. 1027 ¶¶ 24–26). Petitioner also relies on the portion of the '085 patent stating that the transfixation screw hole "may be included in thickened section 136, adjacent to bridge portion 130." *Id.* at 12 (quoting Ex. 1001, 9:6–8). Petitioner contends that the '085 patent touts the advantages of this approach, "nowhere suggests that the transfixation screw hole is part of the bridge portion, as Patent Owner seems to suggest," and also describes the bridge portion as free of voids or holes, contrary to Patent Owner's assertion that Slater's bridge must include the transfixation screw hole. *Id.* (citing Ex. 1001, 8:32–41, 8:60–9:8). Petitioner also asserts, in the alternative, that "[e]ven if the Board allows Patent Owner to pursue a construction that contradicts the intrinsic evidence such that the claimed 'bridge portion' can include voids such as the transfixation screw hole,

141–142 of Dr. Gall's declaration). We do not consider this aspect of Patent Owner's argument as identifying any deficiency in the Petition and do not consider it further.

Slater still discloses this claim element" because "[t]he bridge portion would simply be expanded to include Slater's transfixation screw hole." *Id.* at 13 (citing Ex. 1027 ¶ 27). Petitioner provides an annotated version of Figure 1, reproduced below, to illustrate this position.



The annotated version of Figure 1, like the previous version in the Petition, identifies a "transfixation screw hole" in red with a red arrow pointing to an oval encompassing a hole. Pet. Reply 13. Unlike the annotated version of Figure 1 above, however, the yellow oval identifying the "bridge portion" encompasses the transfixation screw hole. *See id.*

In its Sur-reply, Patent Owner argues that Petitioner improperly changes its position from defining the bridge portion as not including the transfixation screw hole in the Petition to defining the bridge portion as including the transfixation screw hole in its Reply. PO Sur-reply 3–5 (citing Pet. 25; Pet. Reply 13; Ex. 1002 ¶¶ 138–142; Ex. 2003, 51:17–52:7). Patent Owner contends that "such a change in theory as to what the 'bridge portion'

is in Slater in reply should not be permitted." *Id.* at 5. Patent Owner also argues that Petitioner improperly construes "at" to mean "near" because "[s]uch an interpretation is contrary to the specification, which uses the phrase 'adjacent to' when it meant for a desired location to be near something." *Id.* at 5–7 (citing Ex. 1001, 9:6–8).

Based on our review of the arguments and evidence, Petitioner has the better position and establishes that Slater discloses "a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion." We first address Petitioner's primary argument that relies on a bridge portion that does not include the transfixation screw hole. *See* Pet. 24–25. Petitioner's annotated version of Figure 1 and accompanying testimony of Dr. Gall identify the transfixation screw hole directly above, and adjacent to, the bridge portion. *See id.* at 25; Ex. 1002 ¶¶ 141–142. Because we view the limitation "at the bridge portion" as at least encompassing a hole *adjacent to* the bridge portion as the specification describes, we need not reach Petitioner's argument that we should construe "at the bridge portion" to mean "near the bridge portion." *See* Pet. Reply 11. As Petitioner correctly points out, the specification of the '085 patent describes "at the bridge portion" as "adjacent to" the bridge portion. *Id.* at 11–12 ("Dr. Gall's identification of Slater's transfixation screw hole as being adjacent to the bridge portion is consistent with the meaning of "at the thickened portion of the bridge portion" as described in the '085 patent. (EX1002, ¶141; Pet., 24; EX1027, ¶¶24-26). For example, the '085 patent explains that the transfixation screw hole "may be included in thickened section 136, ***adjacent to*** bridge portion 130." (EX1001, 9:6-8)."). The specification also supports this reading, and undermines any reading of "at the bridge portion"

to mean that the hole must be part of the bridge portion because the specification describes the bridge portion as free of voids and holes. Ex. 1001, 8:32–41, 8:60–9:8. Based on our review of the claim language and specification, "at the bridge portion" in claim 1 encompasses "adjacent to" the bridge portion because the specification refers to the transfixation screw hole as being "adjacent to" the bridge portion. *See* Ex. 1001, 8:32–41, 8:60–9:8. With that background in mind, we find that Petitioner establishes that Slater discloses a transfixation screw hole "at," or adjacent to, the bridge portion because the hole appears directly above and adjacent to the bridge portion. Pet. 24–25; Pet. Reply 11–12; Ex. 1002 ¶¶ 141–142; Ex. 1027 ¶¶ 24–26.

Although Patent Owner acknowledges that the specification uses the term "adjacent to" when describing the location of the transfixation screw hole, Patent Owner appears to take the implicit position that "adjacent to" does not describe an embodiment falling within the scope of "at the bridge portion." *See* PO Sur-reply 5–6. We are not persuaded by Patent Owner's approach because (1) it fails to explain why a hole "at the bridge portion" as the claim requires does not encompass what the specification describes as a hole "adjacent to" the bridge portion; (2) Patent Owner does not respond to Petitioner's argument that the specification stresses the advantages of a bridge portion free of voids and holes, which would preclude Patent Owner's implicit reading of "at the bridge portion" that requires a hole on or a part of the bridge portion; and (3) Patent Owner does not cite to any portion of the specification in support of its implicit reading of the claim that shows a transfixation screw hole going through the bridge portion of the plate. *See* PO Resp. 30–32; PO Sur-reply 3–7.

We also agree with Petitioner's alternative argument that if the bridge portion must include the transfixation screw hole, as Patent Owner appears to contend, that Slater discloses such a broadly defined bridge portion. *See* Pet. Reply 13; Ex. 1027 ¶ 27. Patent Owner complains that Petitioner's alternative argument in Reply contradicts Petitioner's argument in the Petition, but we disagree. PO Sur-reply 3–5. We view Petitioner's alternative argument as responsive to Patent Owner's argument in its Response that the bridge must include the transfixation screw hole, which Petitioner could not have reasonable foreseen given that the '085 patent specification describes the hole as adjacent to the bridge and that the bridge preferably lacks voids and holes. *See* Pet. Reply 11–13. Notably, Patent Owner does not argue against the merits of Petitioner's position—that Slater discloses a transfixation screw hole at the bridge portion as required by claim 1 if one defines Slater's bridge portion as encompassing the transfixation screw hole by expanding the area to include the hole. *See id.* at 13; Ex. 1027 ¶ 27; PO Sur-reply 3–5. Given the similarity between the location of the transfixation screw hole in relation to the bridge portion in the '085 patent and Slater, if the '085 patent discloses a bridge portion that includes the transfixation screw hole, then we agree with Petitioner that Slater discloses a bridge portion that includes a transfixation screw hole. *See* Ex. 1001, Fig. 3 (identifying transfixation screw hole 102 and bridge portion 130; Ex. 1005, Fig. 1 (identifying transfixation screw hole and bridge portion spanning the joint); Pet. Reply 13; Ex. 1027 ¶ 27.

Based on the foregoing, we find that Petitioner establishes by a preponderance of the evidence that Slater discloses "a transfixation screw hole disposed along the spine at the thickened portion of the bridge portion."

d. Undisputed Limitations

Petitioner argues that Slater discloses the remaining limitations of claim 1, including the following:

> a plate comprising:
>
> an elongate spine having a first end comprising at least one attachment point for attaching the first end to the first discrete bone on a first side of the joint, a second end comprising at least one attachment point for attaching the second end to the second discrete bone on a second side of the joint, and a bridge portion disposed between the first end and the second end, the bridge portion having a portion configured to span across the joint, . . .; and
>
> an aperture defining a transfixation screw hole disposed along the spine . . ., the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends at a trajectory configured to pass through a first position on the first discrete bone and a second position on the second discrete bone once the plate is placed across the joint.

Ex. 1001, claim 1; Pet. 18–25. For these limitations, Petitioner provides an element-by-element analysis with supporting citations to Slater and the declaration of Dr. Gall. *See id.* (citing various portions of Exhibits 1002 and 1005). With the exception of the arguments we addressed above, Patent Owner does not argue that Petitioner fails to establish that Slater discloses these limitations. *See* PO Resp. 21–32.

We have reviewed Petitioner's arguments and evidence as to the undisputed limitations of claim 1 and find that Petitioner establishes sufficiently that Slater discloses these limitations for the reasons provided by

Petitioner. *See* Pet. 18–25.[10] We need not set forth formal findings as to the undisputed assertions by Petitioner.[11] We adopt Petitioner's arguments and evidence as to these limitations as our own. *See id.*

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[10] The dissent finds that Petitioner fails to establish that Slater discloses the following limitation in claim 1: a "transfixation screw hole comprising an inner surface configured to direct a transfixation screw . . . at a trajectory." More specifically, the dissent finds that Petitioner "failed to provide any meaningful analysis or claim construction that would support a determination that 'at a trajectory' would encompass a transfixation screw hole allowing for a range of trajectories so that Slater's oblong opening 26 would meet the 'trajectory' element of the claims." *See* Dissent, 4. Notably, in this proceeding Patent Owner never argues that Slater fails to anticipate claim 1 because Slater fails to disclose this limitation, and we do not interpret Patent Owner's argument as to a different limitation in dependent claim 8 as applicable to claim 1. We do not view Petitioner's showing as to this limitation as deficient or that Petitioner was required to provide an express construction for "at a trajectory" in the Petition or Reply, especially when Patent Owner never raised the issue in its briefing and we never raised the issue prior to this Final Written Decision. Paper 7, 9 (emphasizing that "any arguments not raised in the [Patent Owner] response may be deemed waived"). Petitioner fully addresses the limitation and provides credible declarant support along with citations to relevant portions of Slater. *See* Pet. 24–25; Ex. 1002 ¶ 142 (citing Ex. 1005, 11:19–25 ("Formation 27 is *configured so that screw 25 is implanted at an angle* within a predetermined allowable angular range.") (emphasis added), 13:21–25 ("Formation 94 is *configured so that a fixation screw is directed at an angle* within a predetermined allowable angular range.") (emphasis added)).

[11] *See In re NuVasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016) ("Although the Board did not make findings as to whether any of the other claim limitations (such as fusion apertures or anti-migration teeth) are disclosed in the prior art, it did not have to: NuVasive did not present arguments about those limitations to the Board . . . . The Board, having found the only disputed limitations together in one reference, was not required to address undisputed matters."); Paper 7, 9 (emphasizing that "any arguments not raised in the response may be deemed waived").

e. Conclusion as to Claim 1

Based on the foregoing, we find that Petitioner proves by a preponderance of the evidence that Slater discloses all of the limitations of independent claim 1 and, therefore, that Slater anticipates claim 1.

2. Claim 6

Claim 6 depends from claim 1 and further recites "wherein the first position resides on a compression side of the joint and the second position resides on a tension side of the joint." Ex. 1001, 13:7–9. Petitioner argues that Slater discloses the limitations of claim 6. Pet. 28–29 (citing Ex. 1002 ¶¶ 149–157). Petitioner contends that the '085 patent defines "neutral bending axis" as "[t]he line about which the force on joint 106 transitions from tension to compression. . . . In other words, neutral bending axis 118 defines the boundary line that separates the tension side of joint 106 from the compression side of joint 106." *Id.* at 28 (citing Ex. 1001, 6:4–10, Fig. 2). Petitioner argues that in "Slater, the axis of the bone plate approximates the direction of the neutral bending axis of the joint between the tibia 4 and talus 3" and that one of ordinary skill in the art "would understand that having a screw cross the joint at the midpoint of the joint would maximize the compressive forces applied across the joint and would cross from the compression side to the tension side of the joint." *Id.* (citing Ex. 1002 ¶¶ 152–156; Ex. 1010 ¶ 49; Ex. 1016 ¶ 35). According to Petitioner, in the context of Slater, "a force in the posterior direction on the foot would place both the tibia and ankle joint in compression on the posterior side of the joint" and "when walking, the first position in Slater on the first bone (tibia 4) will, at some point during the gait cycle, reside on a compression side of the joint and the second position in Slater on the second bone (talus 3) will

reside on a tension side of the joint." *Id.* (citing Ex. 1002 ¶ 157; Ex. 1005, Fig. 1).

Patent Owner argues that "Slater does not disclose a transfixation screw that passes through a compression side of the joint and then the tension side of the joint" because "the ankle joint, for which Slater's plates are designed, does not have a discrete tension and compression side." PO Resp. 33 (citing Ex. 2002 ¶¶ 95–99). Patent Owner contends that, unlike the joint referred to the in '085 patent, "the different portions of the ankle joint are subjected to cyclically changing compression and tension forces" and due to the changes in "force direction, a person of ordinary skill in the art would not refer to the ankle joint as one that has a tension side and a compression side." *Id.* (citing Ex. 2002 ¶¶ 98–99).

In its Reply, Petitioner argues that "Claim 6 does not require a 'discrete' tension side and compression side of the joint" and that "the claim is not expressly limited to a particular joint." Pet. Reply 14 (citing Ex. 1001, claim 6). Petitioner also contends that "[n]othing in the challenged apparatus claim excludes the common scenario where the sides of the joint switch from compression to tension." *Id.* (citing Ex. 1002 ¶ 157).

Based on review of the arguments and evidence, Petitioner establishes that Slater discloses the limitations of claim 6. Petitioner persuasively argues that the axis Slater's bone plate approximates the direction of the neutral bending axis of the joint and that one of ordinary skill in the art "would understand that having a screw cross the joint at the midpoint of the joint would maximize the compressive forces applied across the joint and would cross from the compression side to the tension side of the joint." Pet. 29 (citing Ex. 1002 ¶¶ 152–156; Ex. 1010 ¶ 49; Ex. 1016 ¶ 35). We are

also persuaded that Slater discloses a device that, when used by a patient walking, "a force in the posterior direction on the foot would place both the tibia and ankle joint in compression on the posterior side of the joint" and "the first position in Slater on the first bone (tibia 4) will, at some point during the gait cycle, reside on a compression side of the joint and the second position in Slater on the second bone (talus 3) will reside on a tension side of the joint." *Id.* at 29 (citing Ex. 1002 ¶ 157; Ex. 1005, Fig. 1). Dr. Gall's testimony credibly explains Slater's plate in operation and the compression and tension forces on the ankle joint. *See* Ex. ¶¶ 152–157.

Patent Owner does not directly dispute Dr. Gall's testimony as to how Slater's plate works in operation on an ankle, but does argue that "the ankle joint, for which Slater's plates are designed, does not have a discrete tension and compression side." PO Resp. 33 (citing Ex. 2002 ¶¶ 95–99). These arguments going to the meaning of "compression side" and "tension side" of the joint do not undermine Petitioner's showing here because, as Petitioner correctly points out, "[c]laim 6 does not require a 'discrete' tension side and compression side of the joint" and "is not expressly limited to a particular joint." Pet. Reply 14 (citing Ex. 1001, claim 6). The '085 patent describes how the plate works on a foot and how the metatarso-phalangeal joint 106 flexes, explaining that "the upper or 'dorsal' side of joint 106 will compress together, while the bottom or 'plantar' side of joint 106 will draw apart under tension," which "is generally true for any hinge-type joint." Ex. 1001, 6:1–10. Claim 6, and claim 1 from which it depends, however, do not limit the claimed plate to use on any particular joint or imply that the compression or tension sides of the joint must remain the same when using the claimed plate on a joint. *See id.* at claims 1, 6. Accordingly, although the sides of

the ankle joint in Slater may switch from compression to tension when a patient walks, nothing in the claims excludes these sides of the joint from meeting the "compression side" and "tension side" of the joint limitations in claim 6 at various points in time during the operation of Slater's plate on a foot. *See* Ex. 1002 ¶ 157 (identifying how Slater discloses a compression side and tension side during operation).

Based on the foregoing, we find that Petitioner proves by a preponderance of the evidence that Slater discloses all of the limitations of independent claim 6 and, therefore, that Slater anticipates claim 6.

3. Claims 8 and 9

Claim 8 depends from claim 1 and further recites "wherein: a central axis of the inner surface of the transfixation screw hole defines the trajectory; and the trajectory is configured to cross a neutral bending axis of the joint once the plate is placed across the joint." Ex. 1001, 13:14–18. Claim 9 depends from claim 8. *See id.* at 13:19–20. The "trajectory" claim 8 refers to is the screw trajectory referred to in claim 1. *Id.* at 12:50. According to Petitioner, "Slater discloses that the central axis of the inner surface of the transfixation screw hole (26 or 93) defines a trajectory configured to cross a neutral bending axis of the joint once the plate is placed across the joint." Pet. 31 (citing Ex. 1002 ¶¶ 160–163). Petitioner also contends that Slater's Figure 9 "discloses a central axis of the transfixation screw hole (26 or 93) that defines a trajectory and even identifies an angle associated with that trajectory relative to the axis of the bone plate." *Id.* at 32 (citing Ex. 1002 ¶ 162; Ex. 1005, Fig. 9). Finally, Petitioner argues that Slater's Figure 1 shows that "when the Slater plate is placed across the joint, the trajectory defined by the central axis of the inner

surface of the transfixation hole crosses the neutral bending axis of the joint." *Id.* (citing Ex. 1002 ¶ 163).

Patent Owner argues that "[w]ith respect to the claimed 'central axis,' Petitioners again picks and chooses disclosures from different plates in Slater since no single plate shows the elements as arranged in claim [8][12] of the '085 Patent." PO Resp. 34 (citing Ex. 2002 ¶ 102). Patent Owner contends that Petitioner improperly combines separate embodiments by relying on Figure 9 for its claim 8 argument. *See id.* (citing Ex. 2002 ¶ 167). Patent Owner also argues that Slater's "oblique hole is specifically designed to not have a central axis that defines the screw trajectory" because Slater describes the hole Petitioner relies on as the transfixation screw hole as "oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required." *Id.* at 34–35 (citing Ex. 1005, 16:28–30; Ex. 2002 ¶ 103).

In its Reply, Petitioner argues that Slater's Figure 9 belies Patent Owner's argument that Slater's transfixation screw hole lacks a central axis because Figure 9 shows that "the central axis of Slater's transfixation screw hole forms a 34° angle to the longitudinal axis of the bone plate." Pet. Reply 14 (citing Ex. 1027 ¶¶ 29–30). Petitioner also argues that Figure 9 does not depict a "different plate" that runs afoul of any rule against relying on multiple embodiments. *See id.* at 15.

In its Sur-reply, Patent Owner argues that "Slater allows for 'adjustable orientation' in opening 26 based on 'a predetermined allowable

[12] Patent Owner references claim 2 here in its Response, but we view that reference as a typographical error because claim 2 does not have a "central axis" limitation and the argument appears under a heading for claim 8, which contains that limitation. *See* PO Resp. 34.

angular range,' which Petitioners identify as the transfixation screw hole." PO Sur-reply 10 (citing Pet. 24; Ex. 1005, 11:21–22, 12:23–25). Patent Owner also contends that "Slater fails to disclose a fixed opening for the transfixation screw hole" and that "[r]eading opening 26 as having a fixed trajectory is contrary to the disclosure of Slater." *Id.* at 10. According to Patent Owner, Slater knew how to describe other holes as having a fixed angle but deliberately described transfixation hole 26 using different language, making clear that "[o]pening 26 is meant to be a variable angle hole." *Id.* at 11 (Ex. 1005, 11:15–16, 11:19–22; Ex. 2003, 65:1–4).

We view Patent Owner's interpretation of Slater as more persuasive. *See* PO Resp. 34–35; PO Sur-reply 10–11; Ex. 2002 ¶ 103. Slater describes its hole 26, which Petitioner identifies as the transfixation screw hole, as allowing for "an angle within a predetermined allowable angular range." Ex. 1005, 11:20–23. As Patent Owner correctly points out, directly above this passage Slater describes a different opening having a "predetermined angle," underscoring that Slater's description of hole 26 as allowing for an "allowable range" indicates that it has no such predetermined angle. *See id.* at 11:15–16. Without any predetermined angle, hole 26 lacks a central axis that *defines* a screw directory as the claim requires.

Petitioner argues that Figure 9 shows "the central axis of Slater's transfixation screw hole forms a 34° angle to the longitudinal axis of the bone plate" but nothing in Slater supports Petitioner's position that the *central axis* of the hole forms the angle as the claim requires. Pet. Reply 14 (citing Ex. 1027 ¶¶ 29–30). Instead, in the context of Slater's description of the hole as "oblique" and allowing for a range of angles, the specific angle shown in Figure 9 may merely be one angle within a range of available

angles that are not defined by the central axis. *See* Ex. 1005, 11:20–23, 16:28–30 ("One significant advantage of the plate described herein is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required."). Petitioner does not point to any disclosure in Slater that would suggest the hole shown in Figure 9 includes some different geometry than the same hole Slater describes elsewhere as allowing for a range of angles, such that the central axis of the hole does not "define" the angle of the screw trajectory as claim 8 requires. *See* Pet. 31–32; Pet. Reply 14–15.[13]

Based on the foregoing, we find that Petitioner does not prove by a preponderance of the evidence that Slater discloses all of the limitations of dependent claim 8, and therefore has not shown that claim 8 is unpatentable. Claim 9 depends from claim 8 and our findings as to claim 8 apply equally to claim 9. We find that Petitioner does not prove by a preponderance of the evidence that Slater anticipates claim 9 for the same reasons discussed above in the context of claim 8.

4. Claims 2, 3, and 7

Dependent claims 2, 3, and 7 ultimately depend from claim 1. *See* Ex. 1001, 12:54–13:22. Petitioner argues that Slater anticipates dependent claims 2, 3, and 7. *See* Pet. 26–27, 29–31, 33–34. Petitioner addresses each limitation in these claims, and cites to declarant testimony for support. *See id.* (citing Ex. 1002). With the exception of its arguments as to independent

[13] Because we find that Slater's Figure 9 does not disclose the limitations of claim 8 as Petitioner contends, we need not reach Patent Owner's argument that Petitioner improperly relies on Figure 9 and attempts to combine it with other embodiments in its anticipation analysis. *See* PO Resp. 34.

claim 1, Patent Owner does not address Petitioner's argument and evidence as to claims 2, 3, and 7. PO Resp. 35.

We have reviewed Petitioner's arguments and evidence as to the undisputed limitations of claims 2, 3, and 7 and find that Petitioner establishes that Slater discloses these limitations for the reasons provided by Petitioner. We adopt Petitioner's arguments and evidence as to these limitations as our own. *See* Pet. 26–27, 29–31, 33–34. Based on the foregoing, Petitioner proves by a preponderance of the evidence that Slater anticipates claims 2, 3, and 7.

F. Obviousness of Claims 4 and 5 over Slater and Weaver

Petitioner contends that claims 4 and 5 would have been obvious over Slater and Weaver. Pet. 34–37. Claims 4 and 5 ultimately depend from claim 1 and further require that the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw (claim 4) and threaded to provide a locking interface with a transfixation screw (claim 5). Ex. 1001, 13:1–6. Petitioner alleges that Weaver discloses the limitations in claims 4 and 5 and that it would have been obvious to add Weaver's features to Slater's plate to provide a more secure fixation between the screws and the plate. Pet. 34–37; Ex. 1002 ¶¶ 170–178. Petitioner otherwise relies on its anticipation analysis for claim 1 discussed above. *Id.* at 34.

Patent Owner does not challenge Petitioner's assertion that Weaver discloses the additional limitations of claims 4 and 5 or that one of ordinary skill in the art would have been motivated to combine Slater and Weaver for the reasons provided by Petitioner. *See* PO Resp. 35. Instead, Patent Owner relies on its arguments against Petitioner's challenge to claim 1. *See id.* ("As

detailed above, Petitioners' Ground 1 Slater anticipation theory fails, therefore, Ground 2 fails for the same reasons.").

We have reviewed Petitioner's arguments and evidence as to the undisputed limitations of claims 4 and 5 and find that Petitioner establishes that the combination of Slater and Weaver discloses all of the limitations of claims 4 and 5, and that one of ordinary skill in the art would have been motivated to combine Slater and Weaver for the reasons provided by Petitioner. We adopt Petitioner's arguments and evidence as to these limitations as our own. *See* Pet. 34–37.

Once all relevant facts are found, the ultimate legal determination of obviousness involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan. *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1361 (Fed. Cir. 2017). Above, based on the full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art; and (4) objective indicia of nonobviousness.

In particular, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the art of record; (2) Petitioner establishes that the combination of Slater and Weaver discloses or renders obvious all the limitations of claim 4 and 5; and (3) Patent Owner presents no evidence to establish any objective indicia of nonobviousness. Weighing these underlying factual determinations, Petitioner has shown, by a preponderance

of the evidence, that the combination of Slater and Weaver renders claims 4 and 5 obvious.

G. Anticipation by Falkner and Obviousness Based on Falkner and Arnould

As to Ground 3, Petitioner contends that Falkner anticipates claims 1–8. Pet. 37–52. As to Ground 4, Petitioner argues that dependent claim 9 would have been obvious over Falkner and Arnould. *Id.* at 53–56. Petitioner's argument under Ground 4 relies on Petitioner's predicate anticipation challenge under Ground 3 for claim 1 because claim 9 ultimately depends from claim 1. *Id.* Petitioner relies on Arnould under Ground 4 only for allegedly teaching certain transfixation angles encompassed by claim 9. *See id.* We focus our analysis on Petitioner's anticipation challenge to independent claim 1 because if Petitioner fails to establish that Falkner anticipates independent claim 1, Petitioner's anticipation challenge to dependent claims 2–8 and obviousness challenge to dependent claim 9 fall with its anticipation challenge to claim 1. *See* PO Resp. 45. Patent Owner argues that Falkner fails to anticipate because it does not disclose all of the limitations of claim 1. *Id.* at 36–43.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that Falkner anticipates claim 1. Our analysis follows.

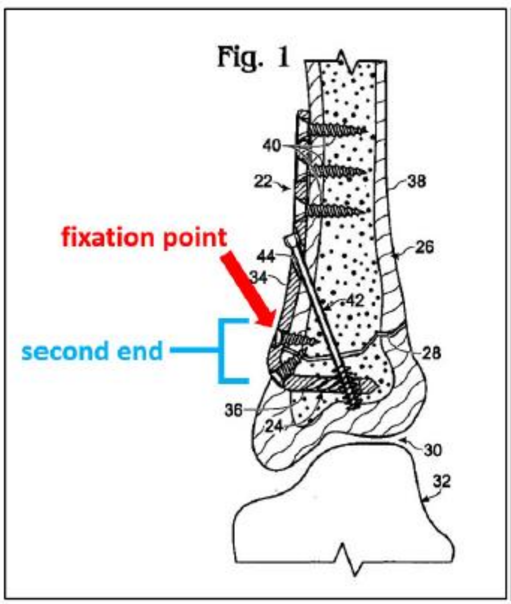
1. The Parties' Contentions

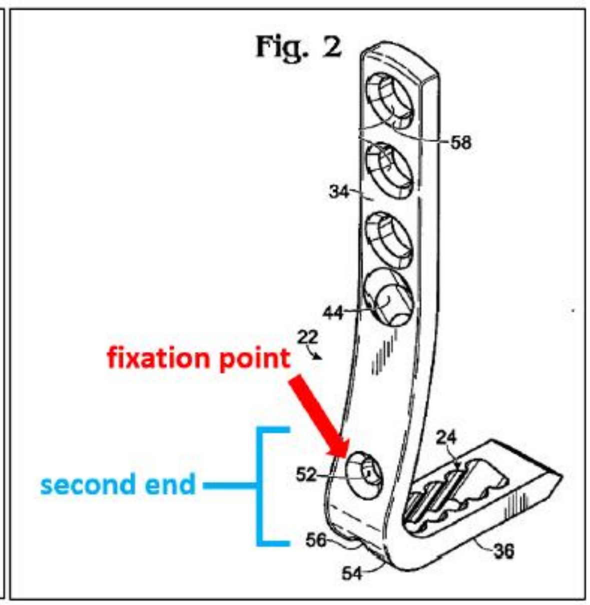
Petitioner alleges that Falkner discloses claim 1's preamble. Pet. 37–38. According to Petitioner, although Falkner's Figure 1 shows a plating system for fixing a single bone having a fracture, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. *Id.* at 38 (citing Ex. 1006 ¶¶ 21, 27–29, 62 (emphasis

omitted)). Petitioner also cites Falkner's disclosure that, in other examples, "plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." *Id.* (emphasis omitted).

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 39 (citing Ex. 1002 ¶ 184). According to Petitioner, this configuration would meet claim 1's "elongate spine" and "first end" limitations. *Id.* at 38–39 (citing Ex. 1002 ¶¶ 182–184).

For claim 1's "second end" limitations, Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.

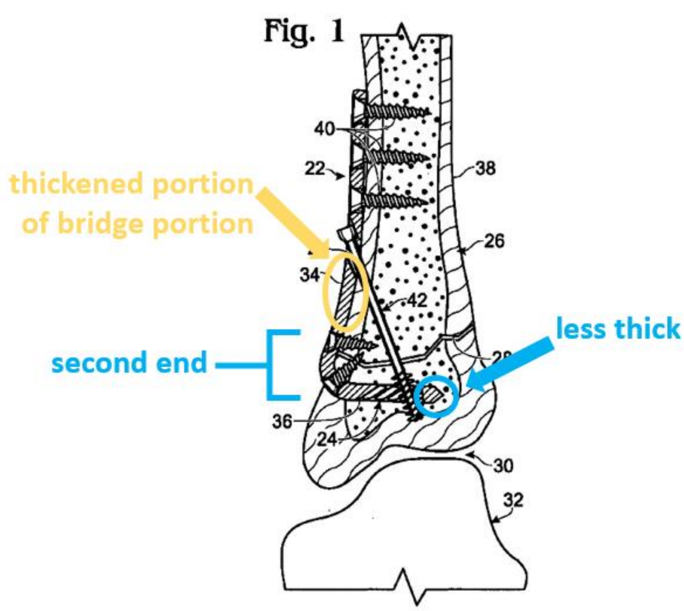




Pet. 40 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated

version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which bracketed segment Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.* With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 40–41 (citing Ex. 1002 ¶ 185).

Turning to claim 1's bridge portion and the requirement that the bridge portion have a depth or thickness greater than a portion of the first or second ends, Petitioner provides another annotation to Falkner's Figure 1. Pet. 42–43. This annotated figure is reproduced below.



Id. at 43; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, above, again shows the Falkner's plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval. Pet. 43. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" has a "thickened portion." *Id.* This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as "less thick," which Petitioner highlights with a blue circle, arrow, and text. *Id.* Petitioner contends that the thickness at the bridge portion appears "thicker" when compared to the tip of internal plate portion 36 inserted into the bone that appears "less thick." Pet. 42–43. Petitioner also relies on Falkner's statement that the "thickness of the plates may vary between plates and/or within plates, according to the intended use," with thicker regions increasing the strength of the plate. *Id.* at 42 (quoting Ex. 1006 ¶ 35). From this, Petitioner argues that "a thickened portion of the claimed bridge portion has a thickness greater than at least a portion of a thickness of either the first end or the second end." *Id.* at 43 (citing Ex. 1002 ¶ 188).

For the transfixation screw hole limitations of claim 1, Petitioner cites Falkner's oblique opening (44) and threaded fastener (42) configured for insertion into said opening. Pet. 43–45. According to Petitioner, "when the Falkner bone plate is configured to span a joint 30 such as tibia 26 and talus 32," oblique opening 44 "is a transfixation screw hole comprising an inner surface configured to direct a transfixation screw (threaded fastener 42) through the oblique opening 44" such that transfixation screw 42 extends at

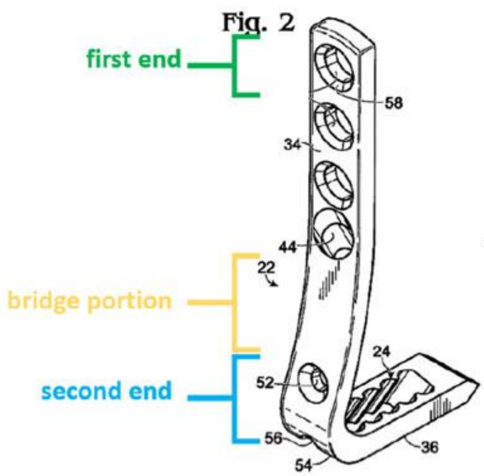
a trajectory configured to pass through the tibia 26 and talus 32 "once the plate is placed across the joint 30." *Id.* at 44–45 (citing Ex. 1002 ¶ 190; Ex. 1006, Fig. 2).

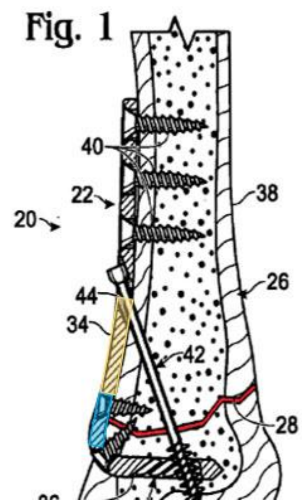
Patent Owner makes three main arguments with regard to independent claim 1. PO Resp. 36–43. First, Patent Owner argues that Falkner fails to disclose a system for securing two discrete bones together across a joint between the two bones. *Id.* at 36–38. Patent Owner contends that Falkner's plate is not designed to secure the two discrete bones across a joint and further contends that "[t]o make a Falkner-type plate that crosses a joint would require extensive modification." PO Resp. 37–38 (citing Ex. 2002 ¶ 109).

Second, Patent Owner argues that Falkner fails to disclose a "second end" that includes "at least one attachment point for attaching the second end to the second discrete bone on a second side of the joint." PO Resp. 39–41. Patent Owner argues that Petitioner improperly relies on hole 52 as the "attachment point" of the "second end" because "the identified attachment point is not on the second bone (or in the case of the Falkner disclosure, on the second part of the fractured bone), but rather above the bone discontinuity on the same side of the bone as the identified first attachment point." *Id.* at 39–40 (citing Ex. 2002 ¶ 112). According to Patent Owner, "[e]ven assuming Dr. Gall is correct that the Falkner blade-plate could simply be shifted down to cross the tibia/talus joint, the second end attachment point that Dr. Gall identifies would actually be on the first bone (i.e., the same side of the joint as the first end attachment point). *Id.* at 40.

Third, Patent Owner contends that Petitioner's modified version of Falkner's plate does not have any portion configured to span across the

bridge portion. *Id.* at 41–43. Patent Owner explains that even if the Falkner plate can be moved across the joint, "the joint would be at the same part of the plate that the bone fracture intersects in Figure 1." *Id.* at 41 (citing Ex. 2002 ¶ 114); *see also id.* ("[T]he *Falkner* blade-plate 'bridge portion' that Petitioners rely upon would not cross the joint at all."). To illustrate that point, Patent Owner references and compares Dr. Gall's annotated image of Falkner's figure 1, shown below on the right, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the left.





Id. at 42 (citing Ex. 1006 Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 186); Ex. 2002 ¶ 118 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 shows a sectional view of a bone plate according to Falkner as it would be applied to a bone. Ex. 1006 ¶ 8. Figure 2 shows a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* ¶¶ 9, 67. Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioner identifies as the "second end." PO Resp. 41–42. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has

identified, highlighted in blue, just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* at 42 (citing Ex. 2002 ¶ 119). Thus, according to Patent Owner, the Falkner plate's alleged bridge portion does not cross the bone discontinuity in Figure 1. Patent Owner further argues that Petitioner recognizes this failing, and improperly shifts its designation of the "bridge portion" in Falkner in an attempt to meet the limitation. *See id.* at 42–43 (citing Ex. 1002 ¶ 186).

In its Reply, Petitioner responds that "Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the specification 'may be positioned on and/or in any suitable bone(s) to span any natural or artificial discontinuity within a bone or between bones.'" Reply 15–16 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new declarant, Dr. Holmes, in support of its position. *See id.* at 17–18 (citing Ex. 1028). Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes' testimony who believes that "Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***." *Id.* at 17 (citing Ex. 1028 ¶¶ 19–20, 25–36). Instead, Petitioners cite to Dr. Holmes who describes a procedure whereby:

> "surgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus" to help create a biomechanically stable joint for fusion. (Ex.1028, ¶¶31-32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Id. Petitioner contends that Falkner expressly enables a person of ordinary skill in the art "to use its bone plate for joint fusion, and teaches all of the structural limitations set forth in the challenged claims." *Id.* at 18.

In its Sur-Reply, Patent Owner responds that Falkner does not disclose the modifications required to anticipate the challenged claim and instead, Petitioner improperly relies heavily on Dr. Holmes' new testimony on how the plate could have been modified. *See* Sur-Reply 11–14. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that the theory of anticipation raised in the Petition is obviousness in disguise." *Id.* at 18. Patent Owner also explains the various ways in which the modifications of the Falkner plate by Dr. Holmes allegedly lack support. *See id.* at 14–22; *see also id.* at 22 ("[T]he extensive modifications required for Falkner's plate to be used across a joint go beyond what reasonably could be anticipation.").

2. Discussion

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. First, we agree with Patent Owner that Petitioner's reliance on the new declaration from Dr. Holmes goes beyond the bounds of permissible argument and evidence in reply. *See* PO Sur-reply 11–14. The 23-page declaration goes into detail as to how a surgeon would use Falkner's plate when spanning two bones. *See* Ex. 1028 ¶¶ 20–36. While some of these opinions are certainly responsive to Patent Owner's arguments and the testimony of Mr. Sommers, much if not all of the material could have been included with the Petition. Falkner contains readily apparent shortcomings

when it comes to its two-bone embodiment because it devotes only a sentence, and no figures, to this possibility. *See* Ex. 1006 ¶ 21. Petitioner should have foreseen the potential shortcomings of Falkner as an anticipatory reference and included a declaration from Dr. Holmes with the Petition. *See* Consolidated Trial Practice Guide (Nov. 2019) ("CTPG"), 73 ("Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g. to make out a prima facie case of unpatentability."), 74–75 ("It is also improper for a reply to present new evidence (including new expert testimony) that could have been presented in a prior filing."). Without the supporting testimony of Dr. Holmes, Petitioner's arguments in its Reply lack adequate support and Patent Owner's arguments in its Response are largely unrebutted.

Second, we agree with Patent Owner that Falkner does not disclose a plate arranged as claimed. PO Resp. 48–49; Ex. 1006, Fig. 1. Falkner's Figure 1 shows a plate *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones. Ex. 1006, Fig. 1. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. *Id.* To make the plate so configured as claimed would require at least some level of redesign or modification. Those might be simple, even arguably obvious, changes for the person of ordinary skill in the art in light of Falkner and its overall teachings, but Petitioner's challenge is based on anticipation. Indeed, Petitioner's and Dr. Gall's repeated invocation of how Falkner's plate, if used in the hypothetical joint-spanning context, "would have been" configured underscores the lack of teaching in Falkner and rings of obviousness, not anticipation. *See, e.g.*, Ex. 1002 ¶¶ 185 ("If the Falkner

plate was used to span a joint between tibia 26 and talus 32, the plate 22 *would have been* placed across the joint 30 and bone screws 40 *would have been* placed into [the bones] . . . and a bone screw 40 *would have been* placed into second discrete bone (talus 32) . . . ."), 187.

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But Falkner provides a dearth of detail about such a hypothetical plate's actual design. On this record, it appears to us that modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met. But, here again, our concern is that such a theory drifts from anticipation—a doctrine still rooted in "strict identity"[14]—to obviousness.

As one example of the problems with Petitioner's arguments, we note that Petitioner cites a portion of Falkner's plate that appears to be close to the middle of the plate and characterizes that portion as a "second end." Pet. 40. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id.* at 43. Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its anticipation position, while purporting to modify other

[14] *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002).

portions of that embodiment in order to render it suitable for a different attachment across multiple bones.[15] Such picking and choosing without adequate explanation undermines the credibility of Petitioner's assertions and suggests that Falkner's plate requires modifications to meet the claim limitations, which is indicative of obviousness. As a whole, we find Patent Owner's arguments and evidence on these issues more persuasive, and the related declarant testimony of Mr. Sommers more credible, and we adopt it as our own findings on these issues. *See* PO Resp. 36–43; PO Sur-reply 14–22.

As noted above, Petitioner's anticipation challenge to dependent claims 2–8 and obviousness challenge to claim 9 based on Falkner and Arnould rely on Petitioner's predicate anticipation analysis as to independent claim 1, which we find unpersuasive for the reasons provided above. *See* Pet. 45–56. For the reasons above, we determine that Petitioner has not demonstrated by a preponderance of evidence that any of claims 1–8 are anticipated by Falkner or that claim 9 would have been obvious over Falkner and Arnould.

---

[15] As a further example, Petitioner identifies opening (52) in Falkner's plate in Figure 1 as the alleged attachment point on a second end of the plate as claimed. Pet. 40. But, as described in Falkner, opening (52) and its corresponding bone screw is fixed on the *same side* of the bone discontinuity (fracture) as the plate portion Petitioner identifies as the plate's first end. Ex. 1006, Fig. 1. Inasmuch as a joint is simply another bone discontinuity in Falkner, Petitioner asserts, with minimal explanation, that a screw would have been placed through opening (52) to secure a second bone (e.g., talus) on the *opposite side* of the joint relative to the plate's first end when the plate is modified for use in this different context. *Id.* at 40–41; Ex. 1002 ¶ 185.

H. Obviousness Based on Arnould and Slater and Obviousness Based on Arnould, Slater, and Weaver

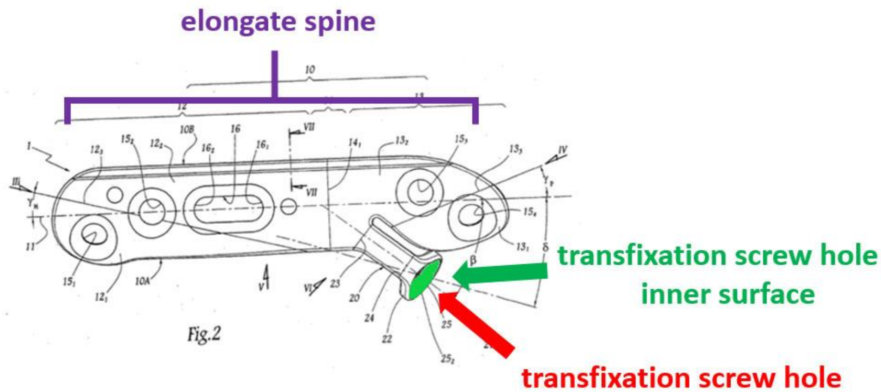
As to Ground 5, Petitioner argues that claims 1–3 and 6–9 would have been obvious over Arnould and Slater. Pet. 56–68. As to Ground 6, Petitioner argues that dependent claims 4 and 5 would have been obvious over Arnould and Slater, in further view of Weaver. Pet. 69–70. Petitioner's reliance on Weaver here is substantially the same as for Ground 2—relying on Weaver's screw locking features and reasons to add them. *Id.* Petitioner's argument under Ground 6 relies on Petitioner's predicate challenge under Ground 5 (which includes claim 1) because claims 4 and 5 ultimately depend from independent claim 1. *Id.* We focus our analysis on Petitioner's challenge to independent claim 1 because if Petitioner fails to establish that claim 1 would have been obvious over Arnould and Slater, Petitioner's obviousness challenges to the dependent claims fall with its challenge to claim 1. *See* PO Resp. 51.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 1 would have been obvious over Arnould and Slater. Our analysis follows.

1. The Parties' Contentions

Petitioner contends that "Arnould discloses each and every element of independent claim 1 except" the element requiring a bridge portion with a thickened section thicker than either the first or second end. Pet. 56 (citing Ex. 1002 ¶ 235). For that missing limitation, Petitioner turns to Slater, which Petitioner argues discloses a thicker bridge portion. *Id.* at 56–57. Petitioner argues that a POSA "would have been motivated to modify the bone plate of Arnould with the thickened bridge portion of Slater in order to

strengthen the bone plate in the region of the bone plate spanning across the joint." *Id.* at 60. As to the limitation in claim 1 requiring "a transfixation screw hole disposed along the spine" of the plate, the Petition relies solely on Arnould for this element. Pet. 62. Petitioner provides an annotated version of Arnould's Figure 2, reproduced below, to illustrate its position.

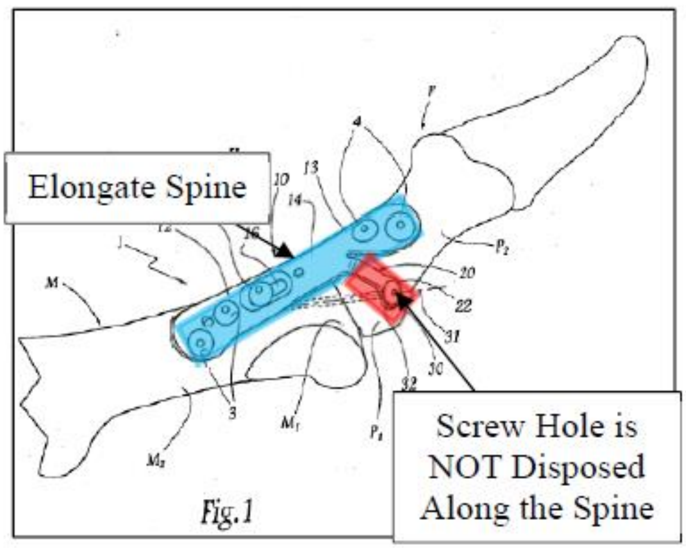


Id. The annotated version of Arnould's Figure 2 identifies a bracketed "elongate spine" in purple at the top of the figure and a "transfixation screw hole" in red at the bottom right of the figure with an arrow pointing to hole 25. *See id.* According to Petitioner,

> Arnould includes an aperture defining a transfixation screw hole (through-hole 25) disposed along the spine (plate body 10) at the thickened portion of the bridge portion (as modified by Slater), the transfixation screw hole (through-hole 25) comprising an inner surface (throughhole edge 25_2) configured to direct the transfixation screw (screw 30) through the transfixation screw hole (through-hole 25) such that the transfixation screw extends at a trajectory (longitudinal axis 31) configured to pass through a first position on the first discrete bone (phalanx P)and a second position on the second discrete bone (metatarsal M) once the plate is placed across the joint.

Id. (citing Ex. 1002 ¶¶ 243–244; Ex. 1008 ¶¶ 6, 8, 23, 26, 27, 32; claims 1, 3; Figs. 1, 2, 5).

Patent Owner contends that Arnould in view of Slater fails to teach the elements of "a transfixation screw hole disposed along the spine." PO Resp. 48–50. Patent Owner contends that the alleged transfixation screw hole of Arnould is a "through-hole 25 (at the end of leg 20[)] . . . [and] is not disposed on the spine, but part of a separate leg piece that extends off the spine." *Id.* at 48. The following annotated version of Arnould's Figure 1 illustrates that point.



Id. at 48 (citing Ex. 1008, Fig. 1; Ex. 2002 ¶ 137). The annotated version of Arnould's Figure 1, above, shows plate (1) having plate body (10) attached to the metatarso-phalangeal bones and joint, and Patent Owner has highlighted in blue the plate's longitudinal body, which Patent Owner calls the "Elongate Spine." *Id.* In red, Patent Owner highlights leg (20), which extends downward from the longitudinal side of the plate body near the plate's midsection. *Id.* Patent Owner also adds an arrow identifying a screw hole at the end of the leg (20), which Patent Owner adds "is NOT Disposed

Along the Spine." *Id.* According to Patent Owner, "there is no reason in view of Arnould to locate a transfixation screw hole along the spine . . . because the explicit advantage of Arnould is that the leg and screw were moved off the spine." *Id.* at 49 (citing Ex. 1008 ¶ 6; Ex. 2002 ¶ 140).

In its Reply, Petitioner argues that "[t]he claim language nowhere equates the 'elongate spine' with the center line of the bone plate." Pet. Reply 25. Petitioner also argues that "Arnould contemplates that various portions of the plate may be bent or curved to conform to the patient's bones." *Id.* at 26. According to Petitioner, "[t]hat Arnould's leg may be bent along two different fold lines to wrap around the phalangeal epiphysis does not mean that the leg is no longer part of the elongate spine." *Id.*

In its Sur-reply, Patent Owner argues that Petitioner fails "to address the express teaching of Arnould that describes 'leg 20'—which the Petition alleges is the claimed 'bridge portion'—being 'located vertically below [the] plate body.'" PO Sur-reply 24 (citing Ex. 1008 ¶ 23). According to Patent Owner, "[s]omething cannot be both along the body (or in the case of the claims, the spine) and below it." *Id.* at 25.

2. Discussion

We have considered Petitioner's arguments and evidence of record, but find Patent Owner to have the better position. In particular, we agree with Patent Owner that Arnould in view of Slater fails to teach or suggest a transfixation screw hole to be deposed along the spine. PO Resp. 48–50. As Patent Owner correctly points out, Arnould discloses that leg (20) "is meant to wrap around the bone and is located vertically below the plate body," which is evident with reference to Figure 1 above. Ex. 1008 ¶ 23. Because

leg 20 extends vertically below the elongate spine, through-hole 25 located at the end of leg 20 resides below and distanced from the elongate spine. *See id.*; Ex. 2002 ¶¶ 138–139. The fact that Arnould touts an advantage stemming from implanting a screw through through-hole 25 supports the testimony of Mr. Sommers that one of ordinary skill in the art reading Arnould would not view through-hole 25 as disposed along the spine. *See* Ex. 1008 ¶ 6; Ex. 2002 ¶ 140.

We have considered but are not persuaded by Petitioner's arguments. For example, Petitioner argues in Reply that "Patent Owner incorrectly re-writes 'disposed along the spine' as 'disposed on the spine,' and improperly narrows the term 'spine' to mean the center line of the bone plate," but we do not view Patent Owner's arguments as that restrictive. *See* Pet. Reply 25 (citing PO Resp. 48). Rather, we agree with Patent Owner that "[s]omething cannot be both along the body (or in the case of the claims, the spine) and below it." Sur-reply 25. Patent Owner does not and need not argue that "disposed along the spine" must be read to mean "disposed on the spine" in order to support its argument because Arnould's spacing of through-hole 25 some distance away from the spine at the end of leg 20 does not satisfy any reasonable interpretation of "along the spine." Petitioner does not provide a supported claim construction for "along the spine" that would support its argument that the limitation encompasses a structure like that Arnould discloses.

Because Petitioner fails to establish that Arnould discloses a transfixation screw hole "disposed along the spine" as required by claim 1, Petitioner fails to establish that claim 1 would have been obvious over Arnould and Slater. As noted above, Petitioner's challenge to dependent

claims 2–3 and 6–9 based on Arnould and Slater and claims 4 and 5 based on Arnould, Slater, and Weaver rely on Petitioner's predicate analysis as to independent claim 1, which we find unpersuasive for the reasons provided above. Pet. 56–68, 69–70. Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that any of claims 2–3 and 6–9 would have been obvious based on Arnould and Slater or that either of claims 4 and 5 would have been obvious based on Arnould, Slater, and Weaver.

CONCLUSION[16]

In summary:

Claims	**35 U.S.C. §**	**Reference(s)/ Basis**	**Claims Shown Unpatentable**	**Claims Not Shown Unpatentable**
1–3, 6–9	102(b)	Slater	1–3, 6, 7	8, 9
4, 5	103(a)	Slater, Weaver	4, 5	
1–8	102(b)	Falkner		1–8
9	103(a)	Falkner, Arnould		9
1–3, 6–9	103(a)	Arnould, Slater		1–3, 6–9
4, 5	103(a)	Arnould, Slater, Weaver		4, 5
Overall Outcome			1–7	8, 9

[16] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–7 of the ’085 patent are determined to be unpatentable;

FURTHER ORDERED that claims 8 and 9 of the ’085 patent are not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Paper 46
Date: March 15, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2021-01450
Patent 8,529,085 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*, dissenting-in-part.

I am pleased to join the Majority Decision ("Dec.") with regard to the determinations reached regarding Petitioner's Falkner and Arnould challenges. Dec. 43–59. I also join the Majority Decision with regard to determinations reached regarding Petitioner's challenge of claims 8 and 9 as anticipated by Slater. *Id.* at 37–39. I do not join the Majority Decision with regard to the unpatentability of challenged claims 1–6 and 7 based on Slater or the combination of Slater and Weaver. Specifically, having considered

the parties' positions and evidence of record, I determine that Petitioner has not demonstrated by a preponderance of evidence that claims 1–3, 6, and 7 are anticipated by Slater. Additionally, I determine that Petitioner has not demonstrated by a preponderance of evidence that claims 4 and 5 would have been obvious over the combination of Slater and Weaver. Accordingly, I respectfully dissent-in-part.

Claim 1 requires a "transfixation screw hole comprising *an inner surface configured to direct a transfixation screw . . . at a trajectory*. Ex. 1001, cl. 1 (emphasis added). Claim 8 further limits that "trajectory" element of claim 1 and further specifies that "a central axis of the inner surface of the transfixation screw hole defines the trajectory." *Id.* at cl. 8. Petitioner contends that openings 26 or 93 disclosed in Slater are a transfixation screw hole that satisfies the "trajectory" element of the claims. Pet. 24–25. Specifically, with reference to claim 1, Petitioner contends that

> While Slater does not explicitly identify openings 26 and 93 as "transfixation screw holes," Slater's disclosure makes it clear that openings 26 and 93 each receive a fixation screw that passes through those openings so that the screw is implanted at an angle. (EX1005, 11:19–21, 13:21–24).

Pet. 24.

In its Response, Patent Owner contends, in the context of claim 8, that,

> the hole Dr. Gall identifies as the transfixation screw hole of Slater again is described as an "oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required." (Ex. 1005, 16:28-30). In other words, the oblique hole is specifically designed to not have a central axis that defines the screw trajectory. (Ex. 2002, ¶ 103). As such, Slater does not anticipate claim 8 of the '085 Patent.

PO Resp. 34–35; *see also id.* at 9 (Patent Owner arguing generally that "[t]he plate described in the '085 Patent also includes a hole at a fixed angle relative to the plate designed to receive a 'transfixation screw.'" (citing Ex. 2002 ¶ 49 (same))). In its Sur-reply, Patent Owner contends that,

> *Slater* fails to disclose a fixed opening for the transfixation screw hole. Reading opening 26 as having a fixed trajectory is contrary to the disclosure of *Slater*. When *Slater* desired for the trajectory of a certain hole to be fixed, it described the hole as such: "formation 13 of opening 12 directs screw 10 at a predetermined angle which optimises fixation." (Ex. 1005, 11:15–16). Opening 26 is meant to be a variable angle hole. (Ex. 1005, 11:19–22 ("an angle within a predetermined allowable angular range"); *see also* Ex. 2003, 65:1–4).

Sur-Reply 11.

Having considered the parties' positions and evidence of record, summarized above, I find that Petitioner fails to sufficiently support its position that Slater discloses a "transfixation screw hole comprising *an inner surface configured to direct a transfixation screw . . . at a trajectory*" as required by the claims. As an initial matter, I note that it is undisputed that Slater's opening 26 is meant to be a variable angle hole and not an opening configured to direct a screw at a particular angle or trajectory. *See* Ex. 1005, 11:19–22 ("an angle within a predetermined allowable angular range"); *see also* Ex. 2003, 65:1–4 (Dr. Gall agreeing that each of the angles depicted by phantom screws shown in Figure 1 of Slater are achieved through the same screw hole 26); Ex. 2002 ¶ 55 ("[Slater's] hole that allows the screw to pass through at multiple angles is described as 'slotted,' which means to me that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles"); Sur-Reply 11.

Petitioner, however, has failed to provide any meaningful analysis or claim construction that would support a determination that "at a trajectory" would encompass a transfixation screw hole allowing for a range of trajectories so that Slater's oblong opening 26 would meet the "trajectory" element of the claims. Moreover, I am unable to discern any support from the prosecution history or specification of the '085 patent that would inform a person of ordinary skill in the art that the recitation of "a transfixation screw hole comprising *an inner surface configured to direct the transfixation screw . . . at a trajectory*" encompasses a transfixation screw hole configured to operate so as to accommodate a range of angles. Pet. 6–10, Ex. 1004. Rather, the specification of the '085 patent repeatedly describes the disclosed plate system as having a transfixation screw hole where it is the inner surface of that hole that is configured to direct a screw at a trajectory, which, according to Mr. Sommers, is language a person of ordinary skill in the art would understand to describe a degree of precision around a single fixed angle. Ex. 1001, 1:43–63; Ex. 2002 ¶ 49; PO Resp. 18–19. For example, the specification describes how "increased plate thickness around transfixation screw hole 102 may also enable transfixation screw hole 102 *to be machined* into bone plate 100 *at an angle* relative to the top surface of bone plate 100." Ex. 1001, 9:13–17 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:64–67; 6:45–66. By comparison, other holes in the disclosed plates are not disclosed with the same level of effort toward precision when describing the trajectory of a screw. Indeed, the specification even includes a description of an oblong opening such as the one found in Slater, described as compression hole 132. *Id.* at 9:20–51.

Petitioner's attempt to interpret the recitation of "a transfixation screw hole comprising *an inner surface configured to direct the transfixation screw . . . at a trajectory*" to encompass Slater's opening 26, configured to operate so as to accommodate a range of angles, attempts to add ambiguity to the scope of the claim without any meaningful attempt at claim construction. Pet. 24. That is improper. *See* 37 C.F.R. § 42.104(b)(3) (the petition must state "[h]ow the challenged claim is to be construed"). A petitioner cannot comply with that obligation by simply implying certain constructions in the Petition without providing any legal or factual support for the constructions. *See* 35 U.S.C. § 312 ("the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, *and the evidence that supports the grounds for the challenge to each claim*.") (emphasis added). The Office's trial practice guide further provides that "where a party believes that a specific term has meaning other than its plain meaning, the party should provide a statement identifying a proposed construction of the particular term and where the disclosure supports that meaning." *See* Trial Practice Guide, 77 Fed. Reg. at 48,764. (emphasis added).

In this case, to support its challenge relying on Slater, it was necessary for Petitioner to propose a construction for "at a trajectory" and explain, under any construction, how the inner surface of Slater's oblong opening 26 is configured to direct a transfixation screw "at a trajectory," which it failed to do. *See* Pet. 11 ("Petitioners have applied the ordinary and customary meaning of each claim term throughout the Petition in light of the 085 patent specification and file history."). For example, it was at least necessary, on this record, for Petitioner to explain how the ordinary and customary

meaning of the phrase "at a trajectory" encompasses an oblong opening capable of accommodating a range of trajectories.

In view of the above, I determine that Petitioner has failed to meet its burden to show that Slater discloses "the transfixation screw hole comprising *an inner surface configured to direct the transfixation screw . . . at a trajectory*." Accordingly, I would conclude that Petitioner has not shown by a preponderance of evidence that claims 1–3, 6 and 7 are anticipated by Slater and, for the same reasons, that Petitioner has not shown by a preponderance of evidence that claims 4 and 5 would have been obvious over the combination of Slater and Weaver. Accordingly, I respectfully dissent-in-part.

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Paper 34
Date: May 30, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2022-00189
Patent 8,529,608 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges.*

Opinion by the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* SNEDDEN.

DECISION
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") and OsteoMed LLC ("Patent Owner"). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claim 16 ("Challenged Claim") of U.S. Patent No. 8,529,608 B2 ("the '608 patent," Ex. 1001) is unpatentable.

A. Background and Summary

Petitioner filed a Petition requesting an *inter partes* review of claim 16 of the '608 patent. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 6.

Following institution, Patent Owner filed a Response to the Petition (Paper 17, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 20, "Reply"), and Patent Owner filed a Sur-reply (Paper 23, "Sur-reply").

On March 1, 2023, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 33.

B. Related Matters

Petitioner filed another petition for *inter partes* review in IPR2021-01450 that challenged claims 1–6, 8–14, and 17 in the '608 patent. Pet. 2; Paper 8, 2. Petitioner has filed petitions for *inter partes* review in IPR2021-01451 and IPR2022-00190 for related U.S. Patent No. 9,351,776; IPR2021-01452 and IPR2022-00191 for related U.S. Patent No. 9,763,716; and IPR2021-01453 for related U.S. Patent No. 10,245,085. Pet. 2–3; Paper 5,

1–2. The parties indicate that the ’608 patent is asserted against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.) and in *OsteoMed LLC v. Wright Medical Technology, Inc.,* Case No. 1:20-cv-1621 (D. Del.). *Id.*

C. The ’608 patent (Ex. 1001)

The ’608 patent discloses a “system for securing bones together across a joint.” Ex. 1001, Abstract. The system may be used for reconstructing a joint that has been damaged due to bone or soft tissue trauma, in which a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint. *Id.* at 1:12–16.

The ’608 patent discloses that its system has “the ability to tightly couple the bones of a joint together” by including a transfixation screw that is inserted across the joint through a bone plate. *Id.* at 2:22–26. More specifically, the ’608 patent discloses that the presence of the transfixation screw across the joint “may increase the contact pressure on the bony interface of the joint, increasing the probability of a positive fusion.” *Id.* at 2:38–41. According to the ’608 patent, by having the transfixation screw passing from the first bone to the second bone, a “tension band” construct is created “that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint,” thereby enhancing the integrity and reliability of the plate and increasing the load that the plate may support without increasing plate thickness. *Id.* at 2:45–52.

Figure 2, reproduced below, shows “a bone plate being used in conjunction with a transfixation screw to repair the failed metatarso-

phalangeal joint" and immediately below it is Figure 3, which shows "a more detailed isometric view of the bone plate." *Id.* at 3:1–6.

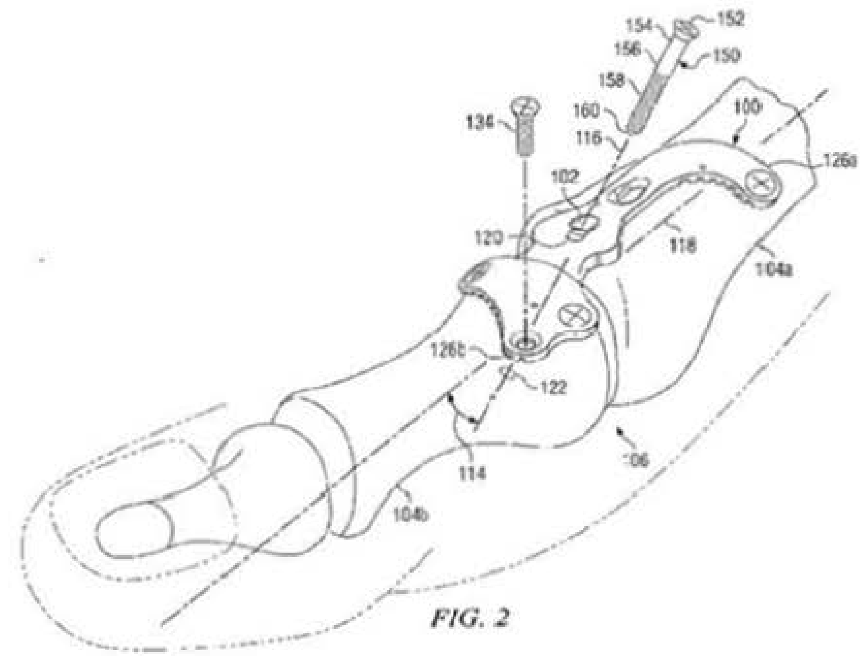


FIG. 2

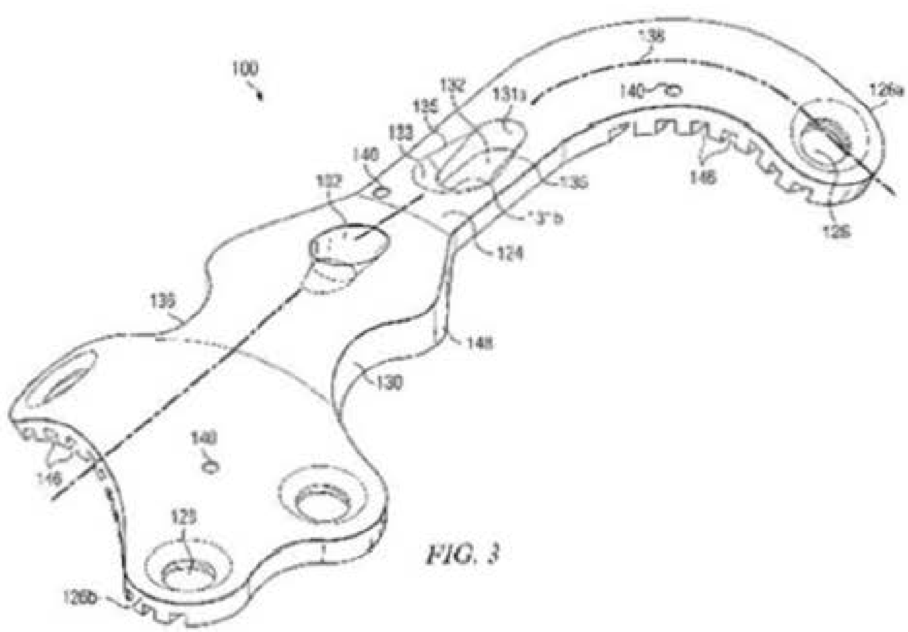


FIG. 3

Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id.* at 4:3–8. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b "in order to fuse joint 106." *Id.* at 4:19–25. Figure 3 shows bone plate 100 having elongated spine 124 and bridge portion 130 between first end 126a and second end 126b that can span across joint 106. *Id.* at 7:18–26. First end 126a includes attachment point 128 "for attaching first end 126a to bone 104a" and second end 126b includes another attachment point 128 "for attaching second end 126b to bone 104b." *Id.* The '608 patent discloses that bridge portion 130 "is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130" and may include thickened section 136 of bone plate 100 "to increase the bending strength of bridge portion 130." *Id.* at 8:2–9.

D. The Sole Challenged Claim

Dependent claim 16, reproduced below, is the only challenged claim of the '608 patent in this proceeding. Claim 16 depends from independent claim 11, which is also reproduced below.

> 11. [11.P] A plate for securing two discrete bones together across an intermediate joint, comprising:
>
> [11.1] an elongate spine having:
>
> a first end comprising:
>
> at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and
>
> a first inner surface configured to substantially conform with a geometry of the first bone;
>
> [11.2] a second end comprising:

at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and

a second inner surface configured to substantially conform with a geometry of the second bone; and

[11.3] a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint; and

[11.4] a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge,

[11.5] wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends.

16. The plate of claim 11, [16.1] further comprising a first flared hip on a first side of the plate and a second flared hip on a second side of the plate, [16.2] the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole.

Ex. 1001, 13:4–14:2, 14:20–25 with Petitioner's numbering added (*see* Pet. 11–12).

E. Evidence

Petitioner relies upon information that includes the following.

Ex. 1005, Slater, WO 2007/131287 A1, published Nov. 22, 2007 ("Slater").

Ex. 1006, Falkner, Jr., U.S. 2005/0171544 A1, published Aug. 4, 2005 ("Falkner").

Ex. 1010, Duncan et al., U.S. 2009/0228048 A1, published Sept. 10, 2009 ("Duncan").

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1028) and Dr. George B. Holmes, Jr. (Ex. 1029) to support its contentions.

Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

F. Asserted Grounds of Unpatentability

Petitioner asserts that claim 16 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	16	102	Slater
2	16	103	Falkner, Duncan

II. ANALYSIS

A. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.* Petitioner states that it has "applied the ordinary and customary meaning of each claim term throughout the Petition in light of the '608 patent specification and file history." Pet. 13

Patent Owner contends that preamble of claim 11 "is limiting, and requires a plate for securing two discrete bones together across a joint between the two bones." PO Resp. 15. Patent Owner also contends that the

term "trajectory" as used in the Challenged Claim "means a fixed angle relative to the neutral bending axis of the joint." *Id.* at 16. Patent Owner's proposed construction is relevant to Ground 1 and our discussion below regarding whether Slater is anticipatory.

Petitioner replies that "Patent Owner fails to demonstrate that the preamble of claim 11 is limiting," because the limitation "a plate ***for*** securing two discrete bones together across a joint" is "an intended use," and "is not a limitation that describes a fundamental characteristic of the claimed invention." Reply 1 (citing *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020) (affirming that preamble phrase "for rehabilitation of unilateral hearing loss" is non-limiting)).

In response, Patent Owner reiterates that the preamble is limiting and that "the limiting language in the preamble was added during prosecution in response to a rejection to limit the claims." Sur-reply 2 (citing Ex. 1004, 267–268, 289, 291, 296).

Having considered the parties' positions and evidence of record, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Petitioner proposes that a person of ordinary skill in the art ("POSA" or "POSITA") at the time of the invention

> would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon.

Pet. 12 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner's proposal about the POSA's qualifications. PO Resp. 22.

For this Decision, we adopt and apply Petitioner's proposal for the POSA level, which does not appear to be inconsistent with the level of skill reflected in the asserted prior art.

C. Summary of Cited Prior Art

1. Summary of Slater (Ex. 1005)

Slater is an international patent application published on November 22, 2007. Ex. 1005, code (43). Slater relates to an ankle fusion plate for fusion of the anterior ankle. *Id.* at 1:6–7. Slater discloses that orthopedic devices can repair diseased bones and bone fractures. *Id.* at 1:21–22. Slater explains that bones that have been fractured must be kept together for lengthy periods of time to permit recalcification and bonding. *Id.* at 3:1–3. According to Slater, internal fixation techniques require "the fracture be stable axially, torsionally and rotationally." *Id.* at 3:19–25; 7:1–2. To achieve such objectives, Slater discloses a fixation screw and plate design in which "the plate depth changes at different locations" so that "the depth at

the beginning a[n]d end points of the L shaped contour [of the plate] over the ankle joint in the second region will be at it[s] maximum thickness." *Id.* at 8:27–34. Slater further discloses that "[t]he plate will taper at least one but preferably two different points of the plate" and that "[t]hese points will preferably resemble and conform to the typical geometry of the anatomical region." *Id.* at 9:3–4, 11–12.

Figure 1, reproduced below, shows a side elevation view of a plate attached via fixation screws "to an abbreviated ankle joint (dotted lines)." *Id.* at 9:28–30.

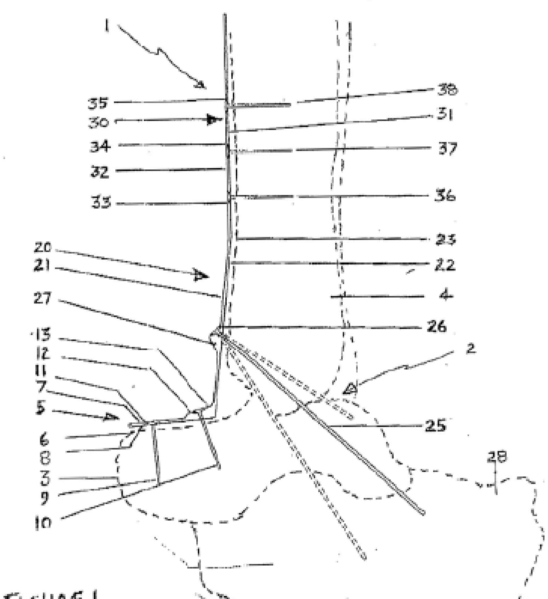


FIGURE 1

Figure 1 shows plate (1) attached to an ankle joint (2) opposing the talus bone (3) and the tibial bone (4). *Id.* at 12:2–4. Figure 1 depicts plate (1) having inner (22) and outer (21) surfaces, with inner surface (22) opposing the anterior surface (23) of the tibia (4). *Id.* at 12:18–19. Portion (30) of the plate includes openings (33, 34, 35) for receiving fastening screws (36, 37, 38), which engage tibia (4). *Id.* at 12:28–31. Portion (5) of the plate has inner (8) and outer (7) surfaces that oppose surface (6) of the

talus bone (3) for fixation thereto by screws (9, 10), which pass through openings (11, 12) and into the talus. *Id.* at 12:5–10.

In addition, portion (20) of Figure 1's plate resides between portions (5) and (30), and includes opening (26) in formation (27), for receiving fixation screw (25). *Id.* at 12:18–22. According to Slater, "[f]ormation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range . . . preferably within a 40 degree arc." *Id.* at 12:21–23; *see also id.* at Fig. 2 (front elevation view of plate 1, showing another view of plate portions (20, 30), openings (33, 34, 35) and formation (27) relative to the underlying anterior tibia (4) and talus (3) to which the plate is attached).

Slater discloses that "[s]crew 25 engages tibia 4, talus 3, and calcaneus 28 [(i.e., heal bone)] effectively providing three points of fixation according to this embodiment." *Id.* at 12:23–25. Continuing, Slater teaches that, "[a]s may be seen in figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis," and "[t]his is also necessary to achieve maximal compression of the fusion site/s." *Id.* at 13:3–5.

In summarizing features of its invention, Slater discloses that the plate's depth may change at different locations and "[p]referably, the depth at the beginning arid [sic, and] end points of the L shaped contour over the ankle joint . . . will be at it's [sic] maximum thickness." *Id.* at 9:31–34; *see also id.* at 10:3–6 ("The plate will taper at least one but preferably two different points of the plate . . . [and] [t]he desired effect is for the plate to taper in and decrease in thickness proximally."). Slater further teaches that the plate "will preferably resemble and conform to the typical geometry of

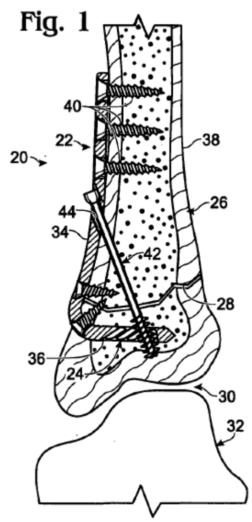
the anatomical region. . . . Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint." *Id.* at 10:11–15.

2. *Summary of Falkner (Ex. 1006)*

Falkner is a U.S. patent application that published August 4, 2005. Ex. 1006, code (43). Falkner relates to systems for fixing bones using bone plates having toothed apertures for retaining fasteners. *Id.* ¶ 7.

Figure 1, reproduced below, shows a cross-sectional view of an exemplary system for fixing bones using a bone plate with a toothed aperture such that the plate is secured to a fractured bone. *Id.* ¶ 8.

Fig. 1



Id. at Fig. 1. Falkner's Figure 1 shows bone plate (22) with toothed aperture (24) attached to the tibia (26) and spanning fracture (28). *Id.* ¶ 21. As illustrated, external plate portion (34) is secured to the tibia with a suitable fastener, such as bone screw (40), and internal plate portion (36) is disposed substantially interior to the tibia. *Id.* ¶¶ 23–24. The internal plate portion (36) defines a toothed aperture (24) configured to receive threaded fastener or screw (42) inserted through opening (44). *Id.* ¶ 24. According to Falkner, "[w]ith the head of the screw engaged with the external plate portion, further

rotation of screw 42 and thus further advancement of threaded region . . . into/through the aperture applies a tension to the plate." *Id.* ¶ 71; *see also id.* at Fig. 2 (showing a more detailed view of toothed aperture (24)).

Although the above embodiment is shown attached to a single bone and spanning a fracture in that bone, Falkner discloses that a plate may be used to span other bone discontinuities—including discontinuities between more than one bone. *Id.* ¶¶ 27–28 (disclosing that discontinuities include fractures (breaks in bones) and joints). Falkner discloses that "[i]n other examples, plate 22 may span a joint, such as a joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21.

Falkner teaches that the inner and outer surfaces of a bone plate "may be generally complementary in contour to the bone surface." *Id.* ¶ 34. Moreover, Falkner discloses, "[t]he thickness of the plates may vary between plates and/or within plates, according to the intended use." *Id.* ¶ 35.

3. Summary of Duncan (Ex. 1010)

Duncan is a U.S. patent application filed March 9, 2009, which published on September 10, 2009. Ex. 1010, codes (22), (43). Duncan relates to a joint fixation system (i.e., plate), especially for the joints of the hand. *Id.* at code (57). Figure 2 of Duncan is reproduced below.

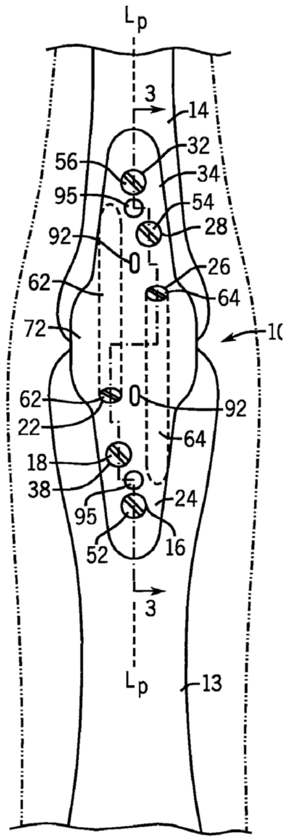


FIG. 2

Id. at Fig. 2. Figure 2, above, is an antero-posterior view of fixation system (10) secured to the proximal interphalangeal joint of a finger. *Id.* ¶ 32.

As shown above, Duncan teaches a joint fixation plate that is widened at an intermediate section (72). *Id.* ¶ 45. This intermediate section is located between the plate's proximal section (24) and distal section (34), and is designed such that screws (64, 62) do not interfere with each other when the screws are inserted, respectively, into proximal phalanx (13) and intermediate phalanx (14). *Id.*

D. Ground 1: Anticipation of Claim 16 by Slater

Petitioner contends that claim 16 is anticipated by Slater. Pet. 18–30. Petitioner begins with its analysis of independent claim 11 (*id.* at 18–28),

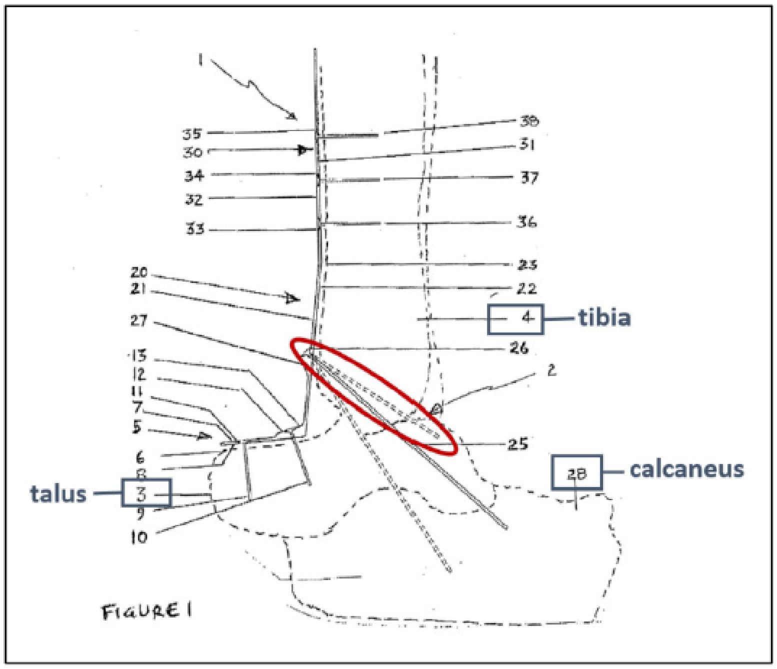
and then addresses the limitations added by dependent claim 16, the sole challenged claim (*id.* at 28–30). Patent Owner raises multiple counterarguments. PO Resp. 22–39.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 16 is anticipated by Slater. Our analysis follows.

1. Petitioner's Contentions

Petitioner first contends that, if claim 11's preamble is limiting, Slater discloses a plate for securing two discrete bones together across an intermediate joint between the bones. Pet. 18–19.[1] In support, Petitioner directs our attention to its annotated Figure 1, reproduced below, which shows "a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines)." *Id.*; Ex. 1005, 9:28–30.

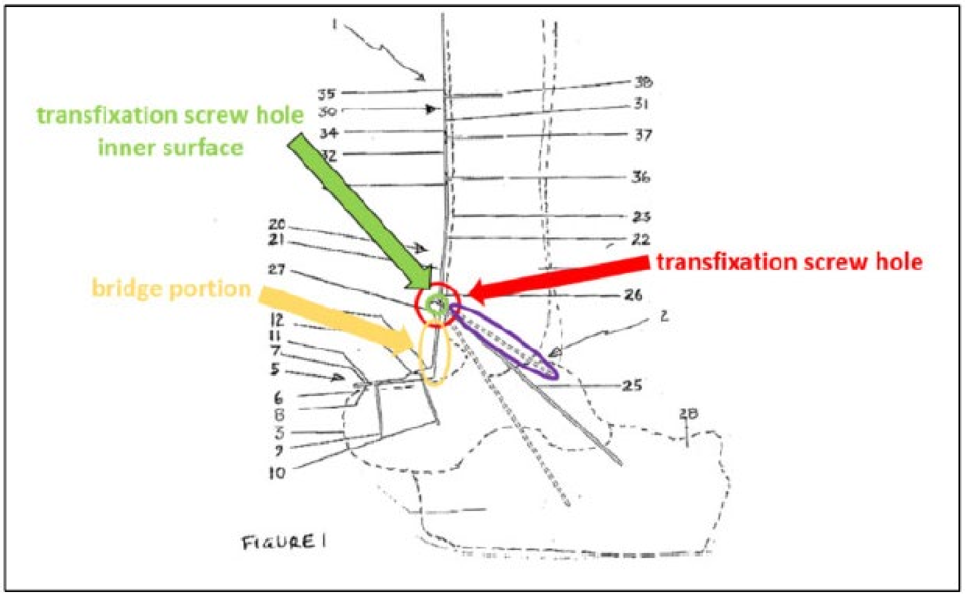
[1] We need not decide whether the preamble is limiting because a system for securing two bones is disclosed in Slater. Moreover, although other portions of claim 11 might limit it to a system for securing two (and only two) bones, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.



Pet. 19. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* Petitioner contends that Figure 1 shows an embodiment where the fusion plate is secured to three discrete bones (tibia, talus, and calcaneus) across two joints between those bones, and also an embodiment where the plate is secured to only two bones (tibia and talus) across one joint between those bones—the latter evidenced by the screw path in the red oval noted above. *Id.* Petitioner supports this interpretation of Slater with Dr. Gall's testimony. *Id.* at 18 (citing Ex. 1002 ¶ 89).

Petitioner further contends that Slater discloses claim 11's elongate spine and first and second ends, as well as a bridge portion between the ends as claimed (labeled by Petitioner as claim limitations 11.1, 11.2, and 11.3). Pet. 19–23 (citing Ex. 1002 ¶¶ 90-94). Petitioner contends that those limitations are disclosed in, for example, Slater's Figure 1 and the features depicted therein. *Id.*

Petitioner also contends that Slater discloses claim 11's recited transfixation screw hole and related functionality, labeled limitation 11.4 by Petitioner. Pet. 24–27. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



Id. at 26. Petitioner's annotation to Figure 1 identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). *Id.* (citing Ex. 1002 ¶ 98). According to Petitioner, "Figure 1 shows three separate exemplary angles for transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3)." *Id.* at 25–26; Ex. 1005, Fig. 1.

According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the

talus through the screw into the screw head and plate's bridge portion as claimed. Pet. 26–27. Petitioner explains that "[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between." *Id.* at 27. Petitioner cites Dr. Gall's testimony to support this understanding of Slater's plate and its functionality when fixed to the tibia and talus as shown. *Id.* (citing Ex. 1002 ¶ 100).

Petitioner next addresses claim 11's recitation of "wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends," which Petitioner labels as limitation 11.5. Pet. 27–28. With reference to Figures 5 and 7 of Slater, Petitioner contends that Slater discloses limitation 11.5. *Id.* (citing Ex. 1005, Figs. 5, 7; Ex. 1002 ¶ 100). In particular, Petitioner contends that "the first and second ends of the Slater bone plate are tapered [, and a]s such, both the bridge portion and the portions of the plate surrounding the transfixation screw hole are thicker than "at least a portion of" the tapered ends." *Id.* (citing Ex. 1002 ¶ 100; Ex. 1005, 8:25–26, 8:32–9:6, 14:19–23, 24:17–19).

Altogether, Petitioner argues that Slater discloses every limitation of claim 11, and Petitioner then turns to dependent claim 16. *Id.* at 28–30. According to Petitioner, Slater also describes a bone plate with flared hips comprising two generally parabolic wings as claimed (labeled limitations 16.1 and 16.2 by Petitioner). *Id.* Petitioner provides an annotated version of Slater's Figure 2, reproduced below.

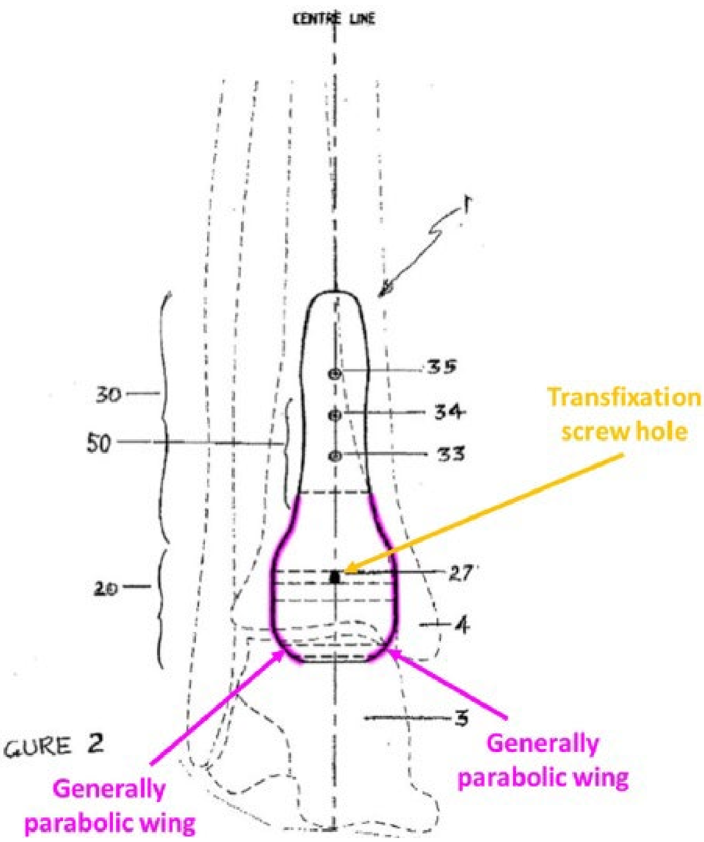


FIGURE 2

Id. at 29. Figure 2, above, is a front elevation view of Slater's plate (the plate as otherwise depicted in a side elevation in Figure 1) and shows the plate oriented for placement on the underlying tibia (4) and talus (3); Petitioner's annotation shows "Generally parabolic wing[s]" (labeled with purple arrows and highlighting) on the lower left and right sides of the plate, extending laterally on opposite sides of the transfixation screw hole (indicated by yellow arrow). *Id.*; Ex. 1002 ¶ 106.

2. *Patent Owner's Response*

Patent Owner contends that "nothing in *Slater* expressly or inherently discloses transferring the tensile load from the second bone through the fixation screw head and into the bridge portion of the plate." PO Resp. 35. Specifically, Patent Owner contends that Petitioner and Dr. Gall improperly assume that Slater discloses a "vise" configuration to transfer tensile load

from the second bone, through the screw and into the bridge portion. *See id* at 36. According to Patent Owner, and its declarant Mr. Sommers, Dr. Gall's assumption depends on the assumption that the threads of Slater's screw 70 would only engage the second bone (the talus) in Slater's two-bone embodiment, but Slater lacks any disclosure to support this assumption. *See id.* at 35–36 (citing Ex. 2002 ¶¶ 106–107; Ex. 2003, 44:21–45:15). Patent Owner argues that Slater does not expressly or inherently disclose Petitioner's "vise" construct, and that Slater fails to disclose how an undisclosed embodiment using the vise approach would transfer tensile load. *Id.* at 36–37 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶¶ 109–110). Patent Owner further contends that Dr. Gall's opinion lacks citations of support to Slater, and any reliance on Slater's finite element analysis lacks support because the test data does not state how the transfixation screw was affixed or loaded, or how many bones it penetrated. *Id.* at 37–38 (citing Ex. 1002 ¶ 99; Ex. 2002 ¶¶ 111–116; Ex. 2003, 92:24–93:7).

3. *Petitioner's Reply*

Petitioner responds that Slater discloses the "vise" configuration because it uses a lag screw "through an angled formation in the bone plate to cross a joint or joints where the screw head is in 'cooperation' with the screw hole," creating a well-known "lag effect" to compress bone parts and absorb tensile load. Reply 13–14 (citing Ex. 1002 ¶ 99; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1027 ¶¶ 121–123; Ex. 1028 ¶¶ 33–42; Ex. 1031, 68:17–70:3, 106:19–107:17; Ex. 2003, 46:23–48:4). Petitioner argues that Mr. Sommers conceded that you only want threads in the second bone, and described transfer of tensile load in the '608 patent in the same manner that Dr. Gall describes Slater transfers

tensile load. *Id.* at 14–15 (citing Ex. 1002 ¶ 99; Ex. 1028 ¶¶ 33–43; Ex. 1031, 74:9–13, 90:24–91:23). Petitioner also argues that "Slater describes in-vivo studies that ***confirm*** tensile load is transferred from the bone to the screw and to the bone plate." *Id.* at 15 (citing Ex. 1005, 17:14–20:26; Ex. 2003, 92:17–93:7; Ex. 1028 ¶¶ 44–45). According to Petitioner, Slater's testing simulated in vivo loading conditions and show that "at least some tensile load is necessarily distributed from the angled screw formation to the bridge portion." *Id.* (citing Ex. 1005, 17:20–21, 19:1–6; Ex. 1028 ¶¶ 45–46; Ex. 1031, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. Analysis

Independent claim 11 recites

> the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, *enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge.*

Ex. 1001, 13:22–31 (emphasis added). We will refer to this limitations collectively as the "transfer of tensile load" limitation. The parties dispute whether Slater expressly or inherently discloses this limitations.

We first address Petitioner's argument that Slater discloses a "vise" configuration, which relies on Petitioner's argument that Slater uses a lag screw with threads on its end that only engage the second bone in Slater's two-bone configuration. *See* Pet. 26–27 (citing Ex. 1002 ¶ 99; Ex. 1005, 11:19–25, 12:32–13:3, 13:21–24); Reply 13–15 (citing Ex. 1002 ¶ 99; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex.

1027 ¶¶ 121–123; Ex. 1028 ¶¶ 33–42; Ex. 1031, 67:23–68:7, 68:17–70:3, 70:16–19, 71:5–9, 74:6–25, 75:5–13, 77:14–22, 106:19–107:17; Ex. 2003, 46:23–48:4, 90:24–91:23). We are not persuaded by Petitioner's argument because Slater does not expressly or inherently disclose how its lag screw threads interact with the first and second bone. Slater's Figure 4 "shows an elevation view of a second screw type 70" having "a longer shank to increase depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone." Ex. 1005, 12:32–13:3. This description of screw type 70 in the *three*-bone configuration does not state that the screw *only* engages the third bone, the calcaneus bone, and describes the "majority of the shank" as "slid[ing] through" holes in the first two bones without stating that none of the threads engage a portion of, for example, the end of the second bone adjacent the third bone. *See id.* More importantly, even if this portion of Slater describes a *three*-bone embodiment where the threads only engage the third bone, Slater provides insufficient support for Petitioner's position that the threads of screw type 70 only engage the second bone in Slater's *two*-bone embodiment, which Petitioner relies on as the anticipatory embodiment of Slater. *See* Pet. 26–27; Ex. 1002 ¶ 99 (arguing that Slater's Figure 1 shows two-bone embodiment). Slater contains no details on this aspect of its alternative two-bone embodiment, such that the threads of the screw may engage the end of the first bone adjacent the second bone and still provide satisfactory results. At best, Petitioner and Dr. Gall's related testimony establish that it would have been desirable, and perhaps obvious, to have the threads of screw type 70 only engage the second bone in Slater's two-bone embodiment to create a

vise-like configuration that transfers tensile load as claimed, but that does not establish that Slater expressly or inherently discloses such an embodiment to satisfy the anticipation standard.

We next address Petitioner's reliance on Slater's finite element analysis tests. *See* Reply 13–15. Petitioner did not rely on this aspect of Slater in the Petition, and raised the argument for the first time in Reply. *Compare* Pet. 26–27, *with* Reply 15. Setting aside the propriety of failing to rely on this aspect of Slater in the Petition, we are not persuaded by Petitioner's argument and evidence for two reasons. First, Petitioner appears to still rely on its argument that Slater discloses a "vise" configuration, and argues that the testing confirms the transfer of tensile load. *See* Reply 13. (relying on "vise" argument), 15 ("Slater describes in-vivo studies that ***confirm*** tensile load is transferred from the bone to the screw and to the bone plate."). Petitioner does not appear to argue that even if we find that Slater does not disclose the "vise" configuration and does not necessarily disclose screw threads that only engage the second bone, that the testing alone shows that Slater discloses the limitation. Reply 15. Accordingly, we do not find the testing argument persuasive due to its link to arguments we find unpersuasive for the reasons discussed above.

Second, Patent Owner correctly points out that Slater provides inadequate information to conclude that the testing results apply to Slater's two-bone configuration such that we can conclude that Slater's two-bone embodiment results in the claimed transfer of tensile load to the plate's bridge. *See* PO Resp. 37–38 (citing Ex. 1002 ¶ 99; Ex. 2002 ¶¶ 111–116; Ex. 2003, 92:24–93:7). Slater's tests merely simulate the response of its plate to certain loads, and do not purport to show actual loading of the plate

on a patient in either the three-bone or two-bone embodiments. Ex. 1005, 17:14–23 (referring to analysis of simulated in-vivo performance and "anticipated loadings" of the plate). Slater also emphasizes that the simulations only apply to "a plate of the particular type and geometry tested" and that "plates with different geometry and dimension . . . may result in different measured loadings and plate response" and "will be likely to have different load capacity results." *Id.* at 20:13–23. Based on the lack of detail as to how Slater's simulations would apply to its two-bone embodiment, and Slater's warning that the simulated results only apply to the specific plate tested, we agree with Patent Owner that Slater's simulated testing does not establish that Slater expressly or inherently discloses the transfer of tensile load limitation in claims 11.

Finally, for similar reasons, we find the testimony of Patent Owner's declarant Mr. Sommers more credible and persuasive than the testimony of Petitioner's declarant Dr. Gall. For example, Dr. Gall opines that Slater discloses a vise configuration, but fails to point to any portion of Slater disclosing that configuration with respect to the two-bone embodiment. *See* Ex. 1002 ¶ 99; Ex. 1027 ¶¶ 33–42. Again, this testimony may establish the desirability of such a configuration and that one of ordinary skill in the art, when using Slater's plate, may do so in the manner Dr. Gall proposes, but that does not establish that Slater expressly or inherently discloses a vise-like configuration due to threaded engagement with only the second bone in Slater's two-bone embodiment. We view the testimony of Mr. Sommers as more credible because it more accurately tracks Slater's disclosures. *See* Ex. 2002 ¶¶ 57–58 (opining that Slater "does not describe whether there would also be threads" in the second of the three bones in the three-bone

embodiment, in practice the threads may engage multiple bones, and Slater does not illustrate or describe how the screw would be used on a two-bone configuration), 81–83, 108–120 (opining that Slater fails to disclose the transfer of tensile load limitations).[2]

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claim 11 and therefore does not prove, by a preponderance of the evidence, that Slater discloses each element of independent claim 11. Petitioner's challenge to dependent claim 16 as anticipated by Slater is substantially similar to its analysis of independent claim 11, which relies on Petitioner's predicate analysis on the independent claim. Pet. 28–29. Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claims 16 is anticipated by Slater.

E. Ground 2: Obviousness of Claim 16 over Falkner and Duncan

Petitioner argues that dependent claim 16 would have been obvious over Falkner and Duncan. Pet. 30–45. As with Ground 1, Petitioner begins with an analysis of independent claim 11 before moving to the challenged dependent claim 16. *Id.* To support its contention, Petitioner directs our attention to the various disclosures of Falkner and provides a detailed claim analysis addressing how each element of claim 11 is disclosed by Falkner.

[2] We are also unpersuaded by Petitioner's arguments based on the alleged similarity between the description Mr. Sommers provides of how the '608 patent shows the transfer of tensile load and Dr. Gall's description of how Slater transfers tensile load. *See* Reply 14–15. It is hardly surprising, and largely irrelevant, that Petitioner's declarant would describe the prior art in a manner consistent with the Patent Owner or its declarant's description of the how the challenged patent works. That similarity alone does not establish that the prior art expressly or inherently discloses the limitation in question.

Pet. 28–36 (citing Ex. 1002 ¶¶ 106–120). Petitioner then directs our attention to the various disclosures of Duncan and provides a detailed claim analysis addressing how each element of claim 16 is disclosed by Duncan, and explains why a person of ordinary skill in the art would have been motivated to modify Faulkner in view of the teachings of Duncan. Pet. 30–45 (citing Ex. 1002 ¶¶ 107–120). Patent Owner raises multiple counterarguments. PO Resp. 39–52.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 16 would have been obvious over Falkner and Duncan. Our analysis follows.

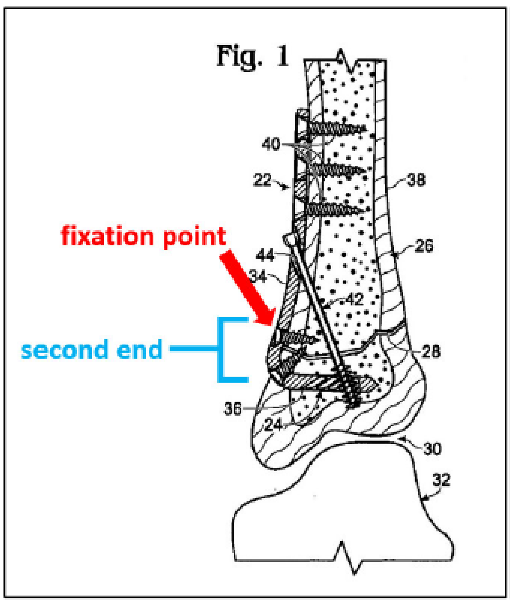
1. Petitioner's Contentions

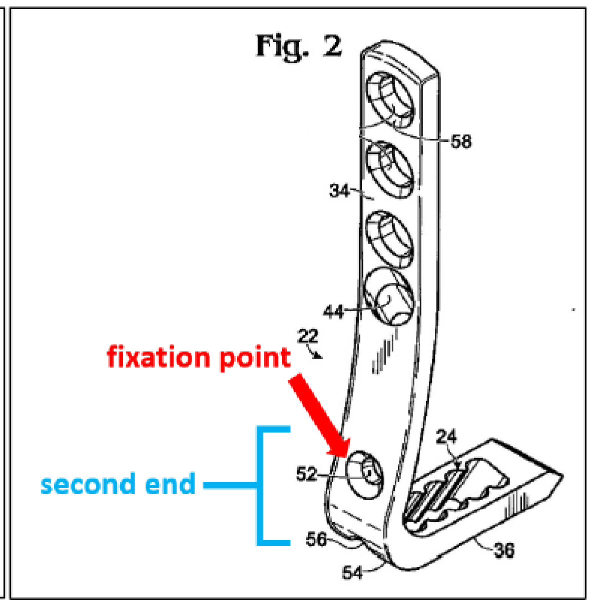
We begin our analysis with Petitioner's contentions with regard to claim 11. Petitioner contends that Falkner discloses the preamble and every other element of claim 11. Pet. 31. According to Petitioner, although Falkner's Figure 1 shows a plate for fixing a single fractured bone, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. Ex. 1006 ¶¶ 21, 28. Petitioner cites Falkner's disclosure that, "[i]n other examples, plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21 (emphasis omitted).

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 32 (citing Ex. 1002 ¶ 111). And, Petitioner argues, "the first inner surface [of the plate] would be configured

to substantially conform with a geometry of the first bone (tibia 26)." *Id.* at 33 (citing Ex. 1002 ¶ 112; and Ex 1006 ¶¶ 23, 34 (disclosures in Falkner that one or multiple surfaces of the bone plate may be contoured to follow the exterior surface of a bone or bones, which helps to provide a low profile to the plate)). According to Petitioner, this configuration would meet claim 11's "elongate spine" and "first end" limitations, of element [11.1]. *Id.*

For claim 11's "second end" limitations (labeled element [11.2] by Petitioner), Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.

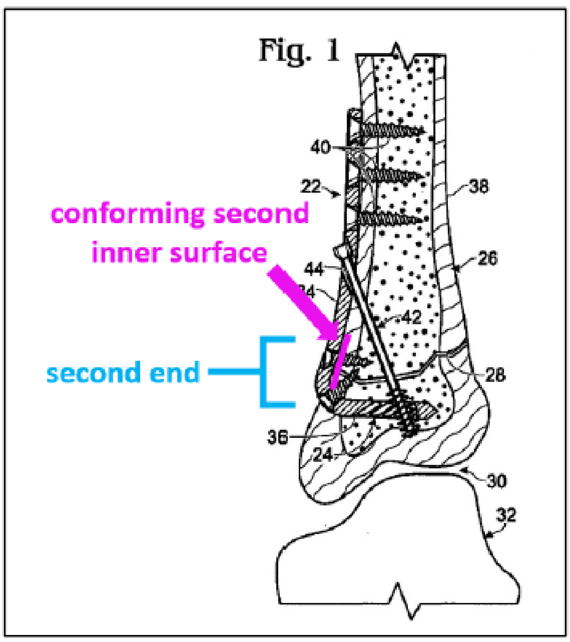




Pet. 34 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22 secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a

blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.*

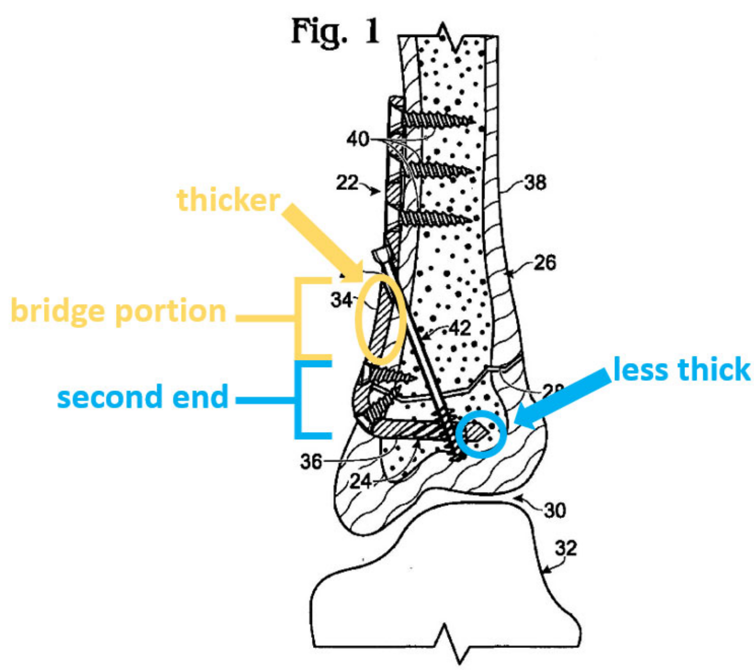
With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia 26 and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 34–35 (citing Ex. 1002 ¶ 113). And, referencing another annotated version of Figure 1 (reproduced below), Petitioner contends that "the second inner surface would be configured to substantially conform with a geometry of the second bone (talus 32)." *Id.* at 35 (citing Ex. 1002 ¶ 114).



Id. at 35; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner's plate attached to the tibia, including Petitioner's blue bracket designating the same alleged "second end," but here, Petitioner

annotates (with purple arrow, line, and text) an alleged conforming "second inner surface." Pet. 35. Petitioner's position appears to be that this purple portion depicted in Figure 1 would be adapted and thus configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. *Id.*

Turning to claim 11's bridge portion and the requirement that a portion of the bridge and transfixation screw hole have a thickness greater than a portion of the first or second ends (elements 11.3 and 11.5), Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 35–36. This annotated figure is reproduced below.



Id. at 39; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, above, shows the same plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval, bracketing, and text. Pet. 39. Petitioner also indicates (with yellow arrow and text) that this

alleged "bridge portion" is thicker." *Id.* This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as being less thick," which Petitioner highlights with a blue circle, arrow, and text. *Id.*

Petitioner argues that, "[a]s can be seen in Figure 1, at least a portion of the bridge portion and the transfixation screw hole (44) has a depth or thickness greater than at least a portion of said first and second ends." *Id.* at 39. According to Petitioner, the alleged "second end" is "thinner at the end" to aid insertion into the bone and becomes thicker toward the bridge to add stability. *Id.* (citing Ex. 1006 ¶ 35).

For the transfixation screw hole and transfixation screw limitations of claim 11.4, Petitioner identifies Falkner's Figures 1 and 2. As shown in those figures, Petitioner cites Falkner's oblique opening (44) in external plate portion (34), and threaded fastener (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate's internal plate portion (36). Pet. 37–38. According to Petitioner, Falkner's oblique opening is a "transfixation screw hole" as claimed, and, in a configuration where Falkner's plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener (i.e., screw) would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* And, in that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred from the talus through the screw and into the bridge portion. *Id.* at 38 (citing Ex. 1002 ¶ 119). In support, Petitioner cites Falkner's teaching that "[w]ith the head of the screw engaged with the external plate portion, further

rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." Pet. 38 (quoting Ex. 1006 ¶ 71).

Having cited disclosure in Falkner that allegedly meets all the limitations of claim 11, Petitioner moves to claim 16 and the recited "flared hip[s]." *Id.* at 40–45. Petitioner cites Duncan's Figure 2, reproduced below with Petitioner's annotations, as teaching the flared hips comprising generally parabolic wings as recited in claim 16.

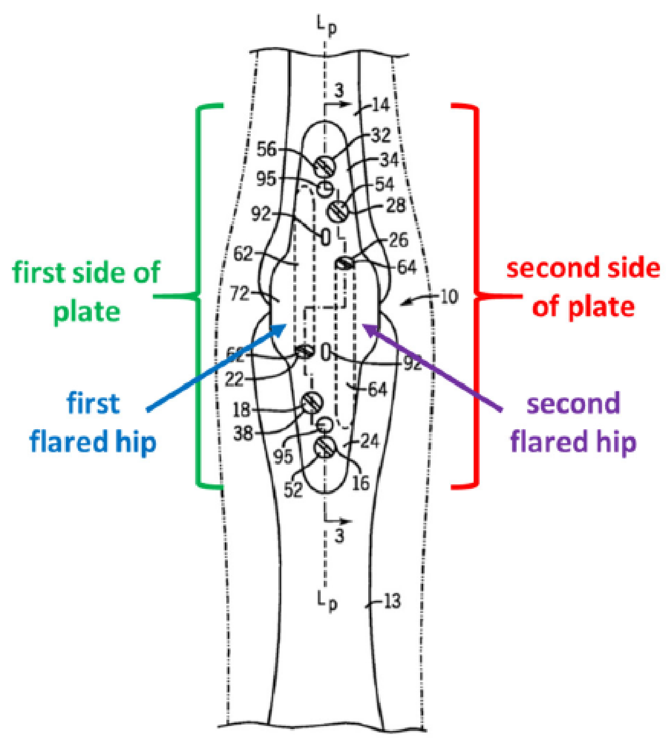


FIG. 2

Id. at 41 (citing Ex. 1016, Fig. 2). Duncan's Figure 2, above, depicts a bone plate (10) attached to two bones (13 and 14) of a finger; Petitioner's annotation highlights the alleged first and second sides of the plate with, respectively, green and red brackets. *Id.* at 41–42. Petitioner identifies, with

blue and purple arrows, the alleged first and second flared hips of the plate on the respective first and second sides of the plate. *Id*. (citing Ex. 1002 ¶¶ 127–131 (testimony that the hips are symmetrically opposed as parabolic wings)).

Petitioner contends it would have been obvious to modify Falkner's plate to include the symmetrically flared hips of Duncan. *Id*. at 42–43. According to Petitioner, a person of ordinary skill in the art would understand that bone plates can be strengthened by making certain portions thicker and wider to counteract higher stress that occurs in those portions. *Id.* (citing Ex. 1002 ¶ 129–130). Petitioner alleges that a person of ordinary skill in the art would understand that including an angled screw hole, such as Falkner's oblique opening (44), results in more plate material being hollowed out such that the plate may require additional strength in those areas. *Id*. at 46 (Ex. 1002 ¶ 128). Petitioner argues that, in addition to thickening the area around the angled screw hole, a POSA would understand that widening the plate around the screw hole will provide added support, and that the need for such support would have motivated a POSA to include flared hips on the plate, such as disclosed in Duncan, particularly if Falkner's plate is designed for use on the medial side of the ankle. *Id*. at 43–44 (citing Ex. 1002 ¶¶ 129–130). Petitioner further contends that a parabolic shape to the hips around the screw hole would help surgeons properly position the plate over the joint. *Id.* at 44 (citing Ex. 1002 ¶ 131). Petitioner argues these changes would have been made with a reasonable expectation of success, predictably adding strength to the plate and adding visual cues to help position the strongest part of the plate over the joint. *Id.*

2. *Patent Owner's Response*

Patent Owner raise multiple counterarguments to Petitioner's Ground 2 and challenges Petitioner's reasoning for combining Falkner and Duncan. *See* generally PO Resp. 39–51.

First, Patent Owner argues that Ground 2 is treated as an "anticipation analysis" with respect to the underlying analysis of independent claim 11 from which challenged claim 16 depends. *Id.* at 39 n.4. But, according to Patent Owner, Falkner "fails to disclose each and every element of [claim 11], arranged as in the claim." *Id.*

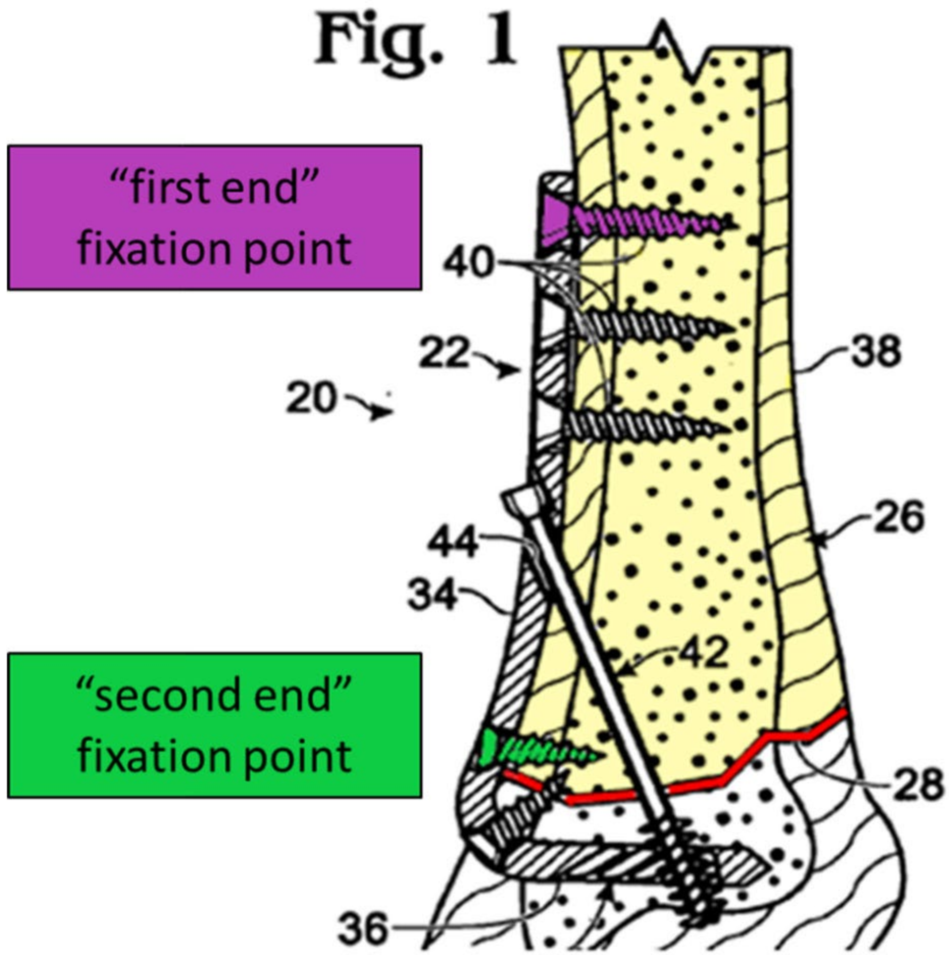
Second, Patent Owner argues that "*Falkner's* plate is not designed to secure 'two discrete bones together across an intermediate joint,'" as seen in "Figure 1 itself, which shows a blade-plate solely on the tibia bone with the talus bone untouched. PO Resp.40 (citing Ex. 2002 ¶ 120). According to Patent Owner, although "*Falkner* explains that this type of blade-plate may be configured to cross a joint rather than a bone fracture, *Falkner* includes 'a dearth of detail about such a hypothetical plate's design.'" *Id.* at 41 (citing Paper 11, 38; Ex. 2002 ¶ 121). Patent Owner contends that Falkner does not disclose a single embodiment that meets all the limitations of claim 11, so Petitioner and Dr. Gall's testimony "far exceeds what is described in the 'four corners of that document [] either expressly or inherently,'" to stretch Falkner's single-bone embodiment to explain how Falkner's plate would have been configured in a different context to reach the claimed subject matter. *Id.* at 42.

Next, Patent Owner argues that Falkner fails to disclose a "second end" that includes a "fixation point" and an "inner surface configured to substantially conform with a geometry of the second bone" as required by

claim 11. *Id.* at 43–47. Patent Owner argues that what Petitioner identifies as the "second end" of Falkner's plate is inside the bone and therefore does not conform to the geometry of the second bone. *Id.* at 45. Patent Owner further contends that:

> With the interior portion of the Falkner blade-plate unable to conform to the geometry of the second discrete bone, the Petition relies on Dr. Gall, rather than the disclosure of Falkner, to conclude that "the plate 22 ***would have been*** placed across the joint 30 and the second inner surface ***would have been*** configured to substantially conform with a geometry of the second discrete bone (talus 32)." (Ex. 1002, ¶ 114 (emphasis added)). That something "would have been configured" is the hallmark of obviousness, and perhaps recognizing this after the fact, Dr. Gall at his deposition seemingly changed course and indicated that a Falkner plate spanning a joint would still include the portion that is interior to the bone. (Ex. 2003, 86:11–15). Therefore, Falkner fails to disclose a second end configured to "substantially conform with a geometry of the second discrete bone."

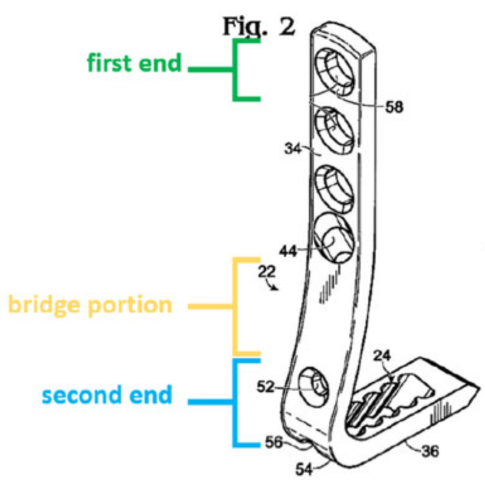
PO Resp. 45–46. Patent Owner asserts that although Petitioner also identifies another portion of the blade-plate as the "second end," Petitioner's "identified fixation point is not on the second bone (or on the second part of the fractured bone) at all." *Id.* at 46 (citing Ex. 2002 ¶¶124–125). According to Patent Owner, "Petitioners rely upon a second end fixation point (green) that is on the **same side** of the bone discontinuity as the first end fixation point (purple), as shown in the annotated image below. *Id.* (citing Ex. 2002 ¶ 125).

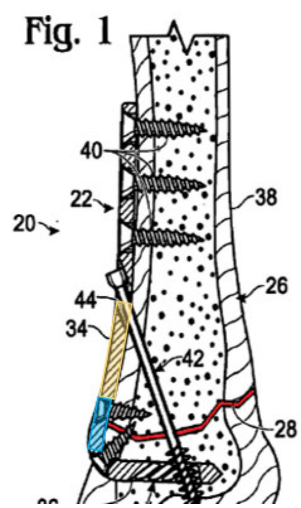


PO Resp. 46 (citing Ex. 1006, Fig. 1). Falkner's Figure 1, above, depicts a bone plate 22 attached to tibia 26; Patent Owner's annotation highlights the alleged first and second fixation points with, respectively, purple and green screws with correspondingly colored label boxes adjacent the screws. *Id.* Patent Owner asserts "[i]f the *Falkner* blade-plate were modified to span a joint rather than a fracture, a POSITA would try to position the plate such that the joint would be in the same location as the fracture shown in Figure 1

to preserve the design intent of the *Falkner* concept." *Id.* (citing Ex. 2002 ¶ 126). Thus, according to Patent Owner, even under this additional "second end" of Falkner, "Falkner fails to meet the "second end" limitations of claim 10. *Id.* (citing Ex. 2002 ¶ 127).

Lastly, Patent Owner contends that Petitioner's modified version of Falkner's plate does not have any portion configured to span across the bridge portion. PO Resp. at 48–50. Patent Owner explains that even if the Falkner plate can be moved across the joint, the plate would cross the "second end", not the bridge portion. *See id.* at 48 ("the *Falkner* blade-plate 'bridge portion' that Petitioners rely upon would not cross the joint at all"). To illustrate that point, Patent Owner references and compares Dr. Gall's annotated image of Falkner's figure 1, shown below on the left, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the right.





Id. at 48–49 (citing Ex. 1006 Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 115); Ex. 2002 ¶ 137 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as in would be applied to a bone. Ex. 1001 ¶ 8. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* ¶¶ 9, 67.

Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioners identify as the "second end." PO Resp. 48. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has identified, highlighted in blue, just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* at 49 (citing Ex. 2002 ¶ 138). Thus, according to Patent Owner, the Falkner plate does not cross the bone discontinuity in Figure 1.

3. *Petitioner's Reply*

In its Reply, Petitioner responds that "Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the [S]pecification 'may be positioned on and/or in any suitable bone(s) to span any natural or artificial discontinuity within a bone or between bones.'" Reply 17 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1029. Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes' testimony who believes that "Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***." Reply 18 (citing Ex. 1029 ¶¶ 19–20, 25–36). Instead, Petitioner cites to Dr. Holmes who describes a procedure whereby:

> [S]urgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus" to help create a biomechanically stable joint for fusion. (Ex.1029, ¶¶31-32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize

> purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Reply 18. Petitioner contends that Falkner "expressly enables a [person of ordinary skill in the art] to use its bone plate for joint fusion, and teaches all of the ***structural*** limitations set forth in the challenged claims." *Id.* at 19.

4. *Patent Owner's Sur-reply*

In its Sur-reply, Patent Owner responds that Falkner does not disclose the modifications required to teach all elements of the challenged claim and instead, the Petitioner relied heavily on Dr. Holmes' testimony on how the plate could have been modified. Sur-reply 11. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that *Falkner's* passing reference to a two-bone embodiment is insufficient to anticipate Claim 11 and insufficient to render the [Claim 16] obvious in view of *Falkner* and *Duncan*." *Id.* at 16–17 (citing, Inst. Dec., 38–39). Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-reply 16–20 ("the extensive modifications required for Falkner's plate to be used across a joint go beyond what reasonably could be anticipation").

5. *Analysis*

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. Petitioner's position does not prevail for at least the reasons set forth on pages 39–50 of the Patent Owner Response and pages 16–20 of the Sur-reply, which we adopt. In particular, we agree with Patent Owner that Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed.

PO Resp. 40–41; Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured as claimed would apparently require at least some level of redesign or modification. Yet, Petitioner cites approvingly to its filing in related IPR2021-01450 as allegedly supporting its challenge here. Pet. 30 ("As an initial matter and as shown below, in the accompanying Declaration, and in earlier-filed IPR2021-1450, *Falkner discloses every element of Claim 11 of the 608 patent*") (emphasis added).

Moreover, to the extent Petitioner's challenge purports to modify Falkner's single-bone embodiment (e.g., as shown in Figures 1 and 2) by citing various other teachings in Falkner, we see minimal analysis that explains why the POSA would have been motivated to make those modifications with a reasonable expectation of success to arrive at claim 11's subject matter. Even when only one reference is involved, the mere fact that each claim limitation might be found in such reference's disclosure does not necessarily prove obviousness without analysis that explains why the skilled artisan would have combined those teachings to arrive at the claimed subject matter. *In re Stepan Co.*, 868 F.3d 1342, 1345–46 n.1 (Fed. Cir. 2017) ("Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, *there must be a motivation to make the combination and a reasonable*

expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.") (emphasis added). Falkner's cited plate in Figures 1 and 2 is not arranged as claimed. Ex. 1006, Fig. 1. It is not configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second discrete bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured would seemingly require redesign or modifications. Those might be simple design changes for a POSA based on their knowledge and Falkner's overall teachings. Petitioner's obviousness analysis on claim 11 is, however, wanting for detail as noted above (e.g., minimal explanation why the POSA would have modified the Falkner plate with a reasonable expectation of success).

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones, including the ankle joint. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But there is a dearth of detail about such a hypothetical plate's actual design. On this record, it appears to us that making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met (e.g., surfaces of the first and second ends that conform to a bone geometry, and a thicker bridge and screw hole portion relative to the ends)., and Petitioner also provides

minimal argument and evidentiary support to explain why all the claimed features would be included. Petitioner argues, for example, that Falkner's Figure 1 shows a portion of a transfixation screw hole that has a thickness greater than a portion of the plate's first and second ends. Pet. 38–40. Neither the identified bridge portion nor screw hole itself appears to have a thickness greater than the plate's first end—claim 11 recites that the thickness be greater than a portion of the *first **and** second ends*. Petitioner briefly remarks that Falkner "contemplates reducing the [plate] thickness of the bone plate to minimize irritation of soft tissue in regions such as the 'first end' of the plate." *Id*. at 39 (citing Ex. 1002 ¶ 120, Ex. 1006 ¶¶ 32, 35). But, on this record, whether Falkner's cited disclosures teach or suggest that the plate's first end, in particular, should be made thinner than the bridge and screw hole portions lacks clarity; and Petitioner does very little to explain why a person of ordinary skill in the art would have been motivated to decrease the thickness at that specific part of the plate.

Moreover, we note that Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate that appears to be close to the middle of the plate and characterizes that portion as a "second end." Pet. 39. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id*. Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its anticipation position with respect to claim 11, while purporting to modify other portions of that embodiment

(e.g., contouring the plate to a particular bony geometry) in order to render it suitable for a different attachment across multiple bones. Such picking and choosing is indicative of obviousness, which as noted above is lacking explanation why the person or ordinary skill in the art would have modified the Falkner plate with a reasonable expectation of success.

Petitioner relies on Duncan principally for its teaching related to the "flared hips" feature (elements 16.1/16.2) of the challenged claim. *Id*. at 40–45. Petitioner's reliance on Duncan and reasoning for adding the flared hips, does not remedy the concerns noted above with Petitioner's showing on the subject matter recited in claim 11.

Accordingly, Petitioner fails to demonstrate by a preponderance of evidence that claim 16 would have been obvious over Falkner and Duncan.

III. CONCLUSION

In summary:

Claim	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
16	102	Slater		16
16	103	Falkner, Duncan		16
Overall Outcome				16

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claim 16 of the '608 patent is not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2022-00189
Patent 8,529,608 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*, concurring.

I concur that Slater does not anticipate claim 16, and reach that result for the following additional reason.

Independent claim 11 recites a "transfixation screw hole comprising *an inner surface configured to direct a transfixation screw* through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion *at a trajectory configured* to pass through a first position on the first bone and a second position on the second bone once the plate is

placed across the joint." Ex. 1001, 13:22–27 (emphasis added). A dispute between the parties is whether the claim recitation for "an inner surface configured to direct the transfixation screw . . . at a trajectory" is taught by Slater. Pet. 25.

To that point, Petitioner contends that Slater identifies openings 26 and 93 that "each receive a fixation screw that passes through those openings so that the screw is implanted at an angle." Pet. 25 (citing Ex. 1005, 11:19–21, 13:21–24, Figs. 1 and 7). More specifically, Petitioner contends that Slater's "transfixation screw hole (26 or 93) . . . comprises an inner surface (unnumbered in Slater's drawings) configured to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first discrete bone (tibia 4), a portion of joint (2) and a second position on the second discrete bone (talus 3) once the plate (1 or 80) is placed across the joint." *Id.* (citing Ex. 1002 ¶ 98; Ex. 1005, 11:19–25, 13:21–25).

In its Response, Patent Owner directs our attention to Figure 1 of Slater, and contends that this Figure "depicts, in phantom, the use of a screw that passes through the tibia and terminates in the talus." PO Resp. 10 (citing Ex. 2002 ¶ 55). "The hole that the screw 25 passes through is constructed in a manner that allows the angle of the screw to be modified as the plate is affixed to the ankle joint." *Id.* (citing Ex. 2002 ¶ 56; Ex. 1005, 11:21–22). "This hole is described as 'slotted,' meaning that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles."

Id. (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8); *see also* Ex. 1005, 16:28–30 ("One significant advantage of the plate described . . . is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required."), Fig. 1.

Furthermore, Patent Owner notes that Slater "provides no detail regarding the structure of the inner surface of the hole" because a surgeon using Slater's plate "determines the path in situ with a range of options available." PO Resp. 33 (citing Ex. 1005, Fig 1; Ex. 2002 ¶ 96). That is, "*Slater* describes a plate that intentionally allows for varied angles through **the same hole**." *Id.* at 33–34 (citing Ex. 1005, 16:28–30 ("[o]ne significant advantage of the plate described [in *Slater*] is the **oblique screw portal allowing for various angles** and the ability to incorporate more joints into the arthrodesis as required"); Ex. 2002 ¶ 102)). Patent Owner contends that, because the hole identified by Petitioner as Slater's transfixation screw hole allows for varied angles through the same hole, Slater fails to disclose a transfixation screw hole having "an inner surface configured to direct the transfixation screw through the transfixation screw hole . . . at a trajectory," where "trajectory" is properly interpreted to mean an "allowable fixed angle relative to the neutral bending axis of the joint." PO Resp. 16–19, 33–35.

In its Reply, Petitioner contends that Patent Owner's suggestion that trajectory limits the challenged claims to a single, fixed angle is "unsupported by the intrinsic evidence." Reply 4. Specifically, Petitioner contends that

> The claims recite only that the claimed "trajectory" is the transfixation screw trajectory, and that such trajectory is configured to pass through "a first position on the first bone and a second position on the second bone" once the plate is placed across the joint. (EX1001, cls. 1, 11). *There is a wide range of*

> *angles at which this can be achieved, not just one fixed angle.* (EX1001, cl. 4; EX1028, ¶11)).

Reply 2 (emphasis added). Petitioner further contends that "the inner surface of the transfixation screw hole does not, alone, determine the precise angle of the trajectory," as "the size, shape, and geometry of the screw also determine what angles the trajectory may have." *Id.* at 3 (citing Ex. 1028 ¶ 12).

Moreover, Petitioner contends that "Patent Owner's reliance on the 'neutral bending axis' as a point of reference for 'trajectory' is nonsensical" because "the neutral bending axis of a particular joint may shift depending on the position of the bone plate and the loads exerted on that joint" and, thus, "the 'trajectory' cannot be known by analyzing a bone plate or system alone." *Id.* at 2–3 (citing Ex. 2002 ¶ 39).

I begin this analysis by clarifying that I understand Patent Owner's position to be that the "inner surface of the transfixation screw hole" is not a hole configured to allow a screw to be inserted into a bone at a plurality of angles, but that the language of the claim requires a configuration that achieves a screw hole that directs a screw at a particular angle (or "trajectory"), where that angle may be configured within a certain range. PO Resp. 18 (citing Ex. 2002 ¶ 95; Ex. 1001, 6:25–30). Thus, the dispute between the parties is whether a singular "inner surface of the transfixation screw hole" may be configured to operate so as to accommodate a range of angles, for example, in the same manner that Slater's oblique screw portal allows for screws to be inserted at varied angles through the same hole. *Id.*; Ex. 1002 ¶ 89 ("One significant advantage of the plate described [in Slater] is the oblique screw portal allowing for various angles and <u>**the ability to incorporate more joints into the arthrodesis**</u> as required.") (quoting Ex.

1005, 16:28–30); Ex. 2002 ¶ 102 (“I agree with Dr. Gall that *Slater* teaches a screw hole that allows a screw to be inserted at a wide range of angles”).

With that important distinction in mind, I consider Patent Owner’s contention that the term “trajectory” as used in the challenged claims means an “allowable fixed angle relative to at least the neutral bending axis of the joint.” PO Resp. 16–19. Here, I note that the challenged claims themselves define what angles are “allowable.” That is, an allowable angle for the transfixation screw is an angle that directs the screw “through a first position on the first bone and a second position on the second bone.” Ex. 1001, 13:25–26, claim 11.

Regarding Patent Owner’s inclusion of the phrase “relative to the neutral bending axis of the joint” in its proposed construction of “trajectory,” I recognize that the specification makes constant reference to the “neutral bending axis” and its relationship to the trajectory is defined by the disclosed transfixation screw hole. *See, e.g.*, Ex. 1001, 1:46–49 (“the trajectory may be configured to cross a neutral bending axis of the joint once the plate is placed across the joint”); *id.* at 2: 42–46 (“the inner surface of the transfixation screw hole in the plate may direct the transfixation screw along a trajectory that crosses a neutral bending axis of the joint”); *id.* at 5:53–57 (“When transfixation screw 150 is screwed into joint 106 along a trajectory that crosses neutral bending axis 118 (as show in FIG. 2), a ‘tension band’ construct is created that puts transfixation screw 150 under tension when joint 106 flexes.”). I also recognize Dr. Gall’s and Mr. Sommer’s statements explaining that the axis of a bone plate may generally approximate the direction of the neutral bending axis of the joint. Ex. 1002 ¶ 128; Ex. 2002 ¶ 93. Furthermore, certain dependent claims, when accounting for the

precise angles recited by those claims, expressly recite angles measured from the neutral bending axis of the joint. *See, e.g.*, Ex. 1001, claim 14 ("wherein the trajectory is configured to pass through the joint at a transfixation angle of about 50 degrees measured from the neutral bending axis."). However, with regard to independent claim 11, I again find that the express recitation of "once the plate is placed across the joint" provides adequate basis for determining how a trajectory is defined, especially in view of Dr. Gall's and Mr. Sommer's testimony, summarized above.[3] Ex. 1001, 13:26–27, claim 11; Ex. 1002 ¶ 128; Ex. 2002 ¶ 93.

The dispositive question is whether the recited transfixation screw hole is configured to direct the transfixation screw on a trajectory that is a fixed angle or is configured to allow for "adjustable orientation" based on "a predetermined allowable angular range" such as opening 26 of Slater, identified by Petitioner as the transfixation screw hole. Pet. 24; Ex. 1005, 12:23–25, 11:21–22. Here, I first note the specification does not describe a plate having a hole identified as a transfixation screw hole that would accommodate insertion of a screw at a plurality of angles through the same hole. Rather, the specification repeatedly describes the disclosed plate system as having a transfixation screw hole where it is the inner surface of that hole that is configured to direct a screw at a trajectory, which, according

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[3] I also note that our express determination of whether a trajectory should be measured from an elongate axis, neutral bending axis of the joint, or otherwise, is unnecessary as such a determination would not affect the outcome of our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

to Mr. Sommers, is language a person of ordinary skill in the art would understand to describe a degree of precision around a single fixed angle. Ex. 1001, 1:26–45, 2:8–14, 2:42–46; Ex. 2002 ¶¶ 50, 95, 97; PO Resp. 17–18. For example, the specification describes how "increased plate thickness around transfixation screw hole 102 may also enable transfixation screw hole 102 *to be machined* into bone plate 100 *at an angle* relative to the top surface of bone plate 100." Ex. 1001, 8:47–52 (emphasis added). In other embodiments, the central axis of the inner surface of the transfixation screw hole defines the trajectory. *Id.* at 1:46–47; 6:19–33. By comparison, other holes in the disclosed plates are not disclosed with the same level of effort toward precision when describing the trajectory of a screw. Indeed, the specification even includes a description of an oblong opening such as the one found in Slater, described as compression hole 132 and serves the purpose of tightening bones so as to "to press together at the interface of joint 106." *Id.* at 8:53–9:26. Taken together, the specification, when read as a whole, describes plates with a transfixation screw hole configured at a single trajectory selected to achieve the functional objectives of the plate, namely, joint fusion, where that single trajectory is preferably between 30 and 70 degrees, and more preferably, 50 degrees. *Id.* at 6:19–33. Petitioner fails to direct us to any example or other disclosure to support its alternative interpretation, namely, a plate configured with a transfixation screw hole 102 configured to permit the placement of a screw at a plurality of trajectories or angles.

Second, other dependent claims support the interpretation of a trajectory configured at a fixed angle. Claim 2, for example, recites that the "central axis of the inner surface of the transfixation screw hole defines the

trajectory," a distinguishing feature as compared to the device in Slater that I will discuss here by way of comparison. Ex. 1001, 12:32–36; *see also id.* at 14:3–7 (claim 12). Figure 1 of Slater depicts, in phantom, the use of screw 25 that passes through the tibia and terminates in the talus. PO Resp. 10 (citing Ex. 2002 ¶ 55). The hole that screw 25 passes through is oblique[4] and allows the angle of the screw to be modified as the plate is affixed to the ankle joint. *Id.* (citing Ex. 2002, ¶ 56; Ex. 1005, 11:21–22). In other words, the oblong hole of Slater is specifically designed to not have a central axis that defines the screw trajectory. (Ex. 2002, ¶ 98); *see also* Ex. 2002 ¶ 97 (Figure 1 of Slater "does not detail anything at all regarding the structure of [the 'inner surface' of the transfixation screw hole], much less demonstrate the hole has an 'inner surface configured to direct the transfixation screw . . . at a trajectory.'").

Claim 4 includes an allowable range between 30 and 70 degrees for the trajectory. Claim 4, however, depends from claim 2, and therefore requires the central axis of the screw hole to define the trajectory of the screw between 30 and 70 degrees. Upon review of this claim structure for the '608 patent, I agree with Patent Owner that a person of ordinary skill in

[4]It is undisputed that the hole identified by Petitioner as the transfixation screw hole is oblong. As noted by Patent Owner, this hole is described as "slotted," which means "that at least a portion of the hole towards the inner surface of the plate is oblong in one direction in order to allow the screw 25 to pass through at multiple angles." PO Resp. 10 (citing Ex. 2002 ¶ 56; Ex. 1005, 24:4–8). Likewise, Dr. Gall recognizes the same hole as the transfixation screw hole of Slater and describes it as an "oblique screw portal allowing for various angles and **<u>the ability to incorporate more joints into the arthrodesis</u>** as required." Ex. 1002 ¶ 102; Ex. 1005, 16:28–30.

the art would understand that, in the context of the intrinsic record, this means that any given plate is configured at a single trajectory or single fixed angle, and that different plates could have a different fixed angle, with plates having single fixed angles in the range between 30 and 70 degrees. PO Resp. 18 (Ex. 2002 ¶ 95; *see also* Ex. 1001, 6:25–30). Here, I also credit Mr. Sommer's explanation that a person of ordinary skill in the art would understand that to mean that a surgeon would be provided with a kit that includes multiple plates, each one with a single fixed angle of, for example, 50, 55, 60, 65 and 70 degrees. Ex. 2002 ¶ 95; Sur-reply 4.

Moreover, claim 5 further limits the trajectory of claim 4 to "a transfixation angle of about 50 degrees measured from the neutral bending axis." Ex. 1001, 12, ll. 49–51; *see also id.* at claim 14. Claim 6 further limits claim 1 and requires that "the inner surface of the transfixation screw hole is configured to lockably engage the head of the transfixation screw," and that engagement of the screw head and screw hole would inherently constrain the configuration of the screw hole to a particular angle. *Id.* at 12, ll. 52–54. Thus, each of dependent claims 2–6, 12, and 14 further limit independent claims 1 and 11 along the lines of a single "trajectory" and are more specifically directed to plates configured with a screw hole that defines a single trajectory.

Finally, while the term "trajectory" used in isolation may not necessarily connote a fixed angle, the assessment here is whether the recitation of an inner surface of a screw configured to direct a screw *at a trajectory* is describing a fixed angle, and more specifically, describing a screw hole configured to direct a screw at a single trajectory. In view of the claim structure of independent claims 1 and 11, the content of the

specification, and testimony of Mr. Sommer's, summarized above, I determine it does. The claims expressly require a transfixation screw hole that itself is "configured to direct the transfixation screw through the transfixation screw hole . . . *at a trajectory*," which in context indicates that a screw hole directs the trajectory of the screw, even if other factors may also influence the trajectory. *Cf.* Reply 2–3. In other words, we agree with Patent Owner that "[a person of ordinary skill in the art] reading [claim 11] in light of the intrinsic record would understand that [the claim language describing the recited screw hole] means that the shape of the inner surface of the transfixation screw hole is such that it guides the screw at a fixed angle." PO Resp. 17; Ex. 2002 ¶ 94.

I recognize Petitioner's argument that "[w]hile Slater's transfixation screw hole allows the transfixation screw to be positioned within a predetermined range, once the screw is threaded into the bone, the screw trajectory, and thus the angle, is fixed," however, I am not persuaded. Reply 12. Petitioner insufficiently explains how the fixation of the angle of the screw trajectory by virtue of being inserted into a bone equates to the claim requirement that the inner surface of the transfixation screw hole directs the screw at a trajectory.

Petitioner's challenge to dependent claim 16 as anticipated by Slater is substantially similar to its analysis of independent claim 11, which relies on Petitioner's predicate analysis on claim 11. *See generally* Pet. That analysis suffers from at least the same shortcomings discussed here for independent claim 11.

In view of the above, I determine that Slater does not disclose "the transfixation screw hole comprising an inner surface configured to direct the

transfixation screw . . . at a trajectory." Slater's opening 26 is meant to be a variable angle hole and not an opening configured to direct a screw at a particular angle or trajectory. *See* Ex. 1005, 11:19–22 ("an angle within a predetermined allowable angular range"); *see also* Ex. 2003, 65:1–4 (Dr. Gall agreeing that each of the angles depicted by phantom screws shown in Figure 1 of Slater are achieved through the same screw hole 26). Accordingly, for this additional reason, I determine that Petitioner has not demonstrated by a preponderance of evidence that claim 16 is anticipated by Slater.

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Paper 33
Date: May 30, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and
WRIGHT MEDICAL TECHNOLOGY, INC.,
Petitioner,

v.

OSTEOMED LLC,
Patent Owner.

IPR2022-00190
Patent 9,351,776 B2

Before SHERIDAN K. SNEDDEN, RICHARD H. MARSCHALL, and JAMIE T. WISZ, *Administrative Patent Judges.*

Opinion by the Board filed by *Administrative Patent Judge* SNEDDEN.

Opinion Concurring filed by *Administrative Patent Judge* SNEDDEN.

DECISION
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Stryker Corporation and Wright Medical Technology, Inc. (collectively, "Petitioner") and OsteoMed LLC ("Patent Owner"). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claim 15 ("Challenged Claim") of U.S. Patent No. 9,351,776 B2 ("the '776 patent," Ex. 1001) is unpatentable.

A. Background and Summary

Petitioner filed a Petition requesting an *inter partes* review of claim 15 of the '776 patent. Paper 2 ("Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 5.

Following institution, Patent Owner filed a Response to the Petition (Paper 16, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 19, "Reply"), and Patent Owner filed a Sur-reply (Paper 22, "Sur-reply").

On March 1, 2023, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 32.

B. Related Matters

Petitioner has filed petitions for *inter partes* review in IPR2021-01450 and IPR2022-00189 for related U.S. Patent No. 8,529,608; IPR2021-01452 and IPR2022-00191 for related U.S. Patent No. 9,763,716; IPR2021-01453 for related U.S. Patent No. 10,245,085. Pet. 1–3; Paper 4, 1–2. The parties indicate that the '776 patent is asserted against Petitioner in *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821 (N.D. Ill.) and in *OsteoMed*

LLC v. Wright Medical Technology, Inc., Case No. 1:20-cv-1621 (D. Del.). *Id.*

Petitioner also filed another petition for *inter partes* review in IPR2021-01451 for the ’776 patent challenging claims 1–6 and 8–13. Pet. 2; Paper 4, 2.

C. The ’776 patent (Ex. 1001)

The ’776 patent discloses a “system for securing bones together across a joint.” Ex. 1001, Abstract. The system may be used for reconstructing a joint that has been damaged due to bone or soft tissue trauma, in which a surgeon may need to fuse the bones of the joint together in a configuration that approximates the natural geometry of the joint. *Id.* at 1:21–25.

The ’776 patent discloses that its system has “the ability to tightly couple the bones of a joint together” by including a transfixation screw that is inserted across the joint through a bone plate. *Id.* at 2:31–35. More specifically, the ’776 patent discloses that the presence of the transfixation screw across the joint “may increase the contact pressure on the bony interface of the joint, increasing the probability of a positive fusion.” *Id.* at 2:46–50. According to the ’776 patent, by having the transfixation screw passing from the first bone to the second bone, a “tension band” construct is created “that enables the transfixation screw to absorb a portion of the mechanical stress that would otherwise be imposed upon the plate above the joint when a load is applied to the joint,” thereby enhancing the integrity and reliability of the plate and increasing the load that the plate may support without increasing plate thickness. *Id.* at 2:54–61.

Figure 2, reproduced below, shows “a bone plate being used in conjunction with a transfixation screw to repair the failed metatarso-

phalangeal joint" and immediately below it is Figure 3, which shows "a more detailed isometric view of the bone plate." *Id.* at 3:9–14.

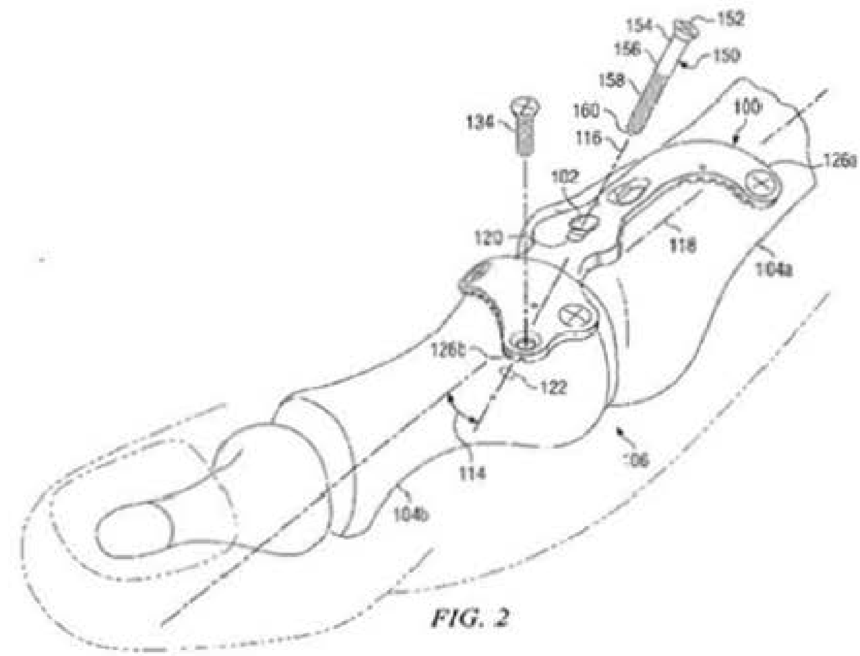


FIG. 2

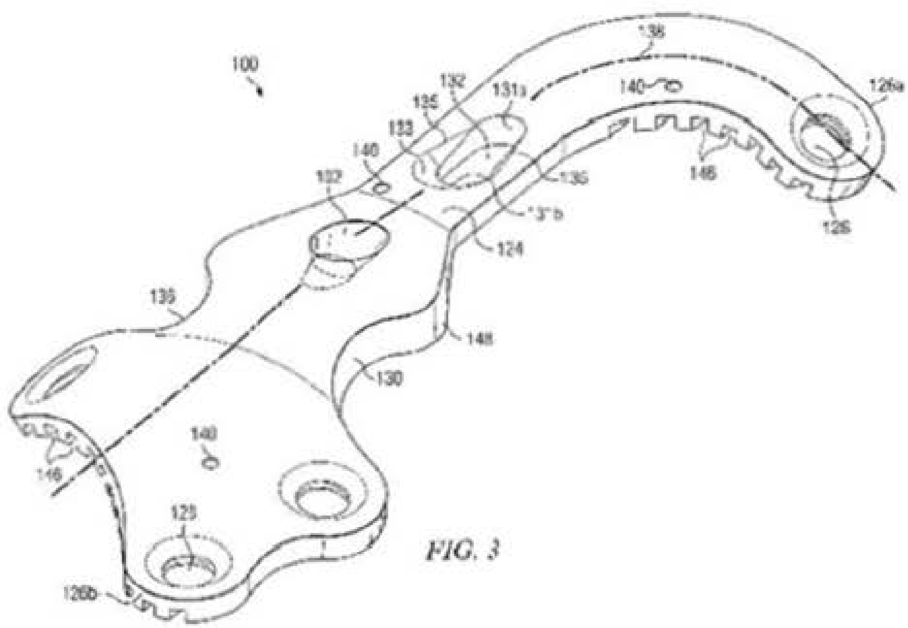


FIG. 3

Figure 2 shows bone plate 100 and transfixation screw 150 applied to a failed metatarso-phalangeal joint. *Id*. at 4:13–15. Transfixation screw 150 is inserted through transfixation screw hole 102 of bone plate 100 and into both first bone 104a and second bone 104b "in order to fuse joint 106." *Id*. at 4:26–30. Figure 3 shows bone plate 100 having elongated spine 124 and bridge portion 130 between first end 126a and second end 126b that can span across joint 106. *Id*. at 7:25–33. First end 126a includes attachment point 128 "for attaching first end 126a to bone 104a" and second end 126b includes another attachment point 128 "for attaching second end 126b to bone 104b." *Id*. The '776 patent discloses that bridge portion 130 "is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130" and may include thickened section 136 of bone plate 100 "to increase the bending strength of bridge portion 130." *Id*. at 8:9–16.

D. The Sole Challenged Claim

Dependent claim 15, reproduced below, is the only challenged claim of the '776 patent in this proceeding. Claim 15 depends from independent claim 10, which is also reproduced below.

> 10. [10.P] A plate for securing two discrete bones together across an intermediate joint, comprising:
>
> [10.1] an elongate spine having:
>
> a first end comprising:
>
> at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and
>
> a first inner surface configured to substantially conform with a geometry of the first bone;
>
> [10.2] a second end comprising:

at least one fixation point for attaching the second end to a second discrete bone on a second side of the joint; and

a second inner surface configured to substantially conform with a geometry of the second bone; and

[10.3] a bridge portion disposed between the first end and the second end, the bridge portion configured to span across the joint; and

[10.4] a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge,

[10.5] wherein at least a portion of said bridge portion and said transfixation screw hole has a depth greater than at least a portion of said first and second ends.

15. The plate of claim 10, [15.1] further comprising a first flared hip on a first side of the plate and a second flared hip on a second side of the plate, [15.2] the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole.

Ex. 1001, 13:3–14:4, 14:22–27 with Petitioner's numbering added (*see* Pet. 12–13).

E. Evidence

Petitioner relies upon information that includes the following.

Ex. 1005, Slater, WO 2007/131287 A1, published Nov. 22, 2007 ("Slater").

Ex. 1006, Falkner, Jr., U.S. 2005/0171544 A1, published Aug. 4, 2005 ("Falkner").

Ex. 1010, Duncan et al., U.S. 2009/0228048 A1, published Sept. 10, 2009 ("Duncan").

Petitioner also relies upon the Declarations of Dr. Kenneth A. Gall (Ex. 1002 and Ex. 1028) and Dr. George B. Holmes, Jr. (Ex. 1029) to support its contentions.

Patent Owner relies upon the Declaration of Mr. Mark B. Sommers (Ex. 2002).

F. Asserted Grounds of Unpatentability

Petitioner asserts that claim 15 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	15	102	Slater
2	15	103	Falkner, Duncan

II. ANALYSIS

A. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner states that it has "applied the ordinary and customary meaning of each claim term throughout the Petition in light of the '776 patent specification and file history." Pet. 14.

Patent Owner contends that the preamble of claim 10 "is limiting, and requires a plate for securing two discrete bones together across a joint between the two bones." PO Resp. 15. Patent Owner also contends that the term "trajectory" as used in the Challenged Claims "means a fixed angle relative to the neutral bending axis of the joint." *Id.* at 16. Patent Owner's proposed construction is relevant to Ground 1 and our discussion below regarding whether Slater is anticipatory.

Petitioner replies that "Patent Owner fails to demonstrate that the preamble of claim 10 is limiting," because the limitation "a plate ***for*** securing two discrete bones together across a joint" is "an intended use," and "is not a limitation that describes a fundamental characteristic of the claimed invention." Reply 1 (citing *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020) (affirming that preamble phrase "for rehabilitation of unilateral hearing loss" is non-limiting)).

In response, Patent Owner reiterates that the preamble is limiting and that "the limiting language in the preamble was added during prosecution of Application No. US 12/431,017, the parent application of the '776 Patent, in response to a rejection to limit the claims." Sur-reply 2 (citing Ex. 1004, 267–268, 289, 291, 296).

Having considered the parties' positions and evidence of record, we determine that no express construction of any claim term is necessary to determine whether to institute *inter partes* review. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). To the extent

further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Petitioner proposes that a person of ordinary skill in the art ("POSA" or "POSITA") at the time of the invention

> would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon.

Pet. 13 (citing Ex. 1002 ¶¶ 35–39). Patent Owner does not dispute Petitioner's proposal about the POSA's qualifications. PO Resp. 22.

For this Decision, we adopt and apply Petitioner's proposal for the POSA level, which does not appear to be inconsistent with the level of skill reflected in the asserted prior art.

C. Summary of Cited Prior Art

1. Summary of Slater (Ex. 1005)

Slater is an international patent application published on November 22, 2007. Ex. 1005, code (43). Slater relates to an ankle fusion plate for fusion of the anterior ankle. *Id.* at 1:6–7. Slater discloses that orthopedic devices can repair diseased bones and bone fractures. *Id.* at 1:21–22. Slater explains that bones that have been fractured must be kept together for lengthy periods of time to permit recalcification and bonding. *Id.* at 3:1–3.

According to Slater, internal fixation techniques require "the fracture be stable axially, torsionally and rotationally." *Id*. at 3:19–25; 7:1–2. To achieve such objectives, Slater discloses a fixation screw and plate design in which "the plate depth changes at different locations" so that "the depth at the beginning a[n]d end points of the L shaped contour [of the plate] over the ankle joint in the second region will be at it[s] maximum thickness." *Id*. at 8:27–34. Slater further discloses that "[t]he plate will taper at least one but preferably two different points of the plate" and that "[t]hese points will preferably resemble and conform to the typical geometry of the anatomical region." *Id*. at 9:3–4, 11–12.

Figure 1, reproduced below, shows a side elevation view of a plate attached via fixation screws "to an abbreviated ankle joint (dotted lines)." *Id*. at 9:28–30.

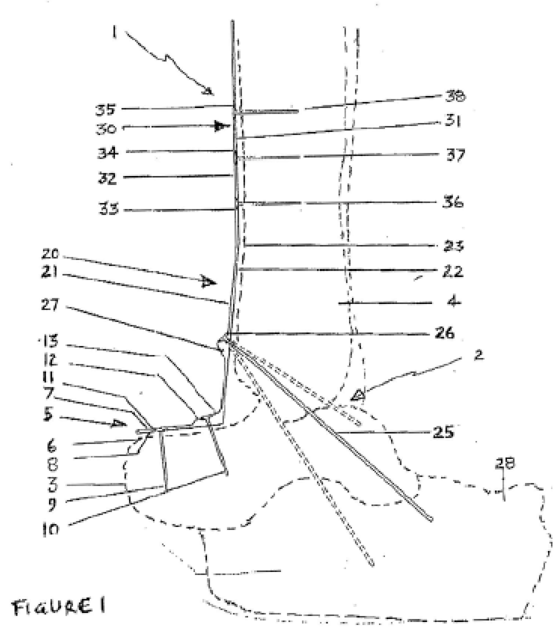


Figure 1 shows plate (1) attached to an ankle joint (2) opposing the talus bone (3) and the tibial bone (4). *Id*. at 12:2–4. Figure 1 depicts plate (1) having inner (22) and outer (21) surfaces, with inner surface (22)

opposing the anterior surface (23) of the tibia (4). *Id.* at 12:18–19. Portion (30) of the plate includes openings (33, 34, 35) for receiving fastening screws (36, 37, 38), which engage tibia (4). *Id.* at 12:28–31. Portion (5) of the plate has inner (8) and outer (7) surfaces that oppose surface (6) of the talus bone (3) for fixation thereto by screws (9, 10), which pass through openings (11, 12) and into the talus. *Id.* at 12:5–10.

In addition, portion (20) of Figure 1's plate resides between portions (5) and (30), and includes opening (26) in formation (27), for receiving fixation screw (25). *Id.* at 12:18–22. According to Slater, "[f]ormation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range . . . preferably within a 40 degree arc." *Id.* at 12:21–23; *see also id.* at Fig. 2 (front elevation view of plate 1, showing another view of plate portions (20, 30), openings (33, 34, 35) and formation (27) relative to the underlying anterior tibia (4) and talus (3) to which the plate is attached).

Slater discloses that "[s]crew 25 engages tibia 4, talus 3, and calcaneus 28 [(i.e., heal bone)] effectively providing three points of fixation according to this embodiment." *Id.* at 12:23–25. Continuing, Slater teaches that, "[a]s may be seen in figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis," and "[t]his is also necessary to achieve maximal compression of the fusion site/s." *Id.* at 13:3–5.

In summarizing features of its invention, Slater discloses that the plate's depth may change at different locations and "[p]referably, the depth at the beginning arid [sic, and] end points of the L shaped contour over the ankle joint . . . will be at it's [sic] maximum thickness." *Id.* at 9:31–34; *see*

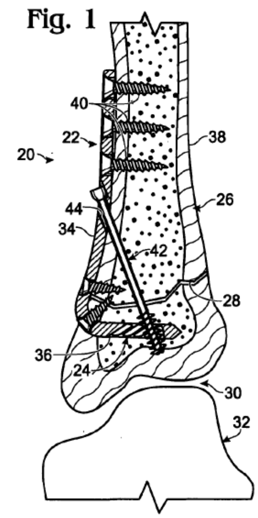
also id. at 10:3–6 ("The plate will taper at at least one but preferably two different points of the plate . . . [and] [t]he desired effect is for the plate to taper in and decrease in thickness proximally."). Slater further teaches that the plate "will preferably resemble and conform to the typical geometry of the anatomical region. . . . Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint." *Id.* at 10:11–15.

2. Summary of Falkner (Ex. 1006)

Falkner is a U.S. patent application that published August 4, 2005. Ex. 1006, code (43). Falkner relates to systems for fixing bones using bone plates having toothed apertures for retaining fasteners. *Id.* ¶ 7.

Figure 1, reproduced below, shows a cross-sectional view of an exemplary system for fixing bones using a bone plate with a toothed aperture such that the bone plate is secured to a fractured bone. *Id.* ¶ 8.

Fig. 1



Id. at Fig. 1. Falkner's Figure 1 shows bone plate (22) with toothed aperture (24) attached to the tibia (26) and spanning fracture (28). *Id.* ¶ 21. As illustrated, external plate portion (34) is secured to the tibia with a suitable fastener, such as bone screw (40), and internal plate portion (36) is disposed substantially interior to the tibia. *Id.* ¶¶ 23–24. The internal plate portion

(36) defines a toothed aperture (24) configured to receive threaded fastener or screw (42) inserted through opening (44). *Id.* ¶ 24. According to Falkner, "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region . . . into/through the aperture applies a tension to the plate." *Id.* ¶ 71; *see also id.* at Fig. 2 (showing a more detailed view of toothed aperture (24)).

Although the above embodiment is shown attached to a single bone and spanning a fracture in that bone, Falkner discloses that a plate may be used to span other bone discontinuities—including discontinuities between more than one bone. *Id.* ¶¶ 27–28 (disclosing that discontinuities include fractures (breaks in bones) and joints). Falkner discloses that "[i]n other examples, plate 22 may span a joint, such as a joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21.

Falkner teaches that the inner and outer surfaces of a bone plate "may be generally complementary in contour to the bone surface." *Id.* ¶ 34. Moreover, Falkner discloses, "[t]he thickness of the plates may vary between plates and/or within plates, according to the intended use." *Id.* ¶ 35.

3. Summary of Duncan (Ex. 1010)

Duncan is a U.S. patent application filed March 9, 2009, which published on September 10, 2009. Ex. 1010, codes (22), (43). Duncan relates to a joint fixation system (i.e., plate), especially for the joints of the hand. *Id.* at code (57). Figure 2 of Duncan is reproduced below.

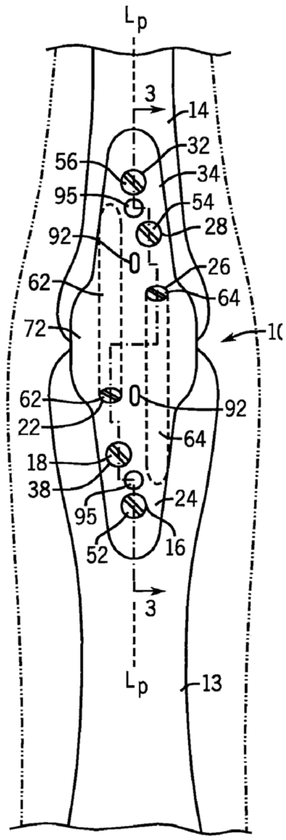


FIG. 2

Id. at Fig. 2. Figure 2, above, is an antero-posterior view of fixation system (10) secured to the proximal interphalangeal joint of a finger. *Id.* ¶ 32.

As shown above, Duncan teaches a joint fixation plate that is widened at an intermediate section (72). *Id.* ¶ 45. This intermediate section is located between the plate's proximal section (24) and distal section (34), and is designed such that screws (64, 62) do not interfere with each other when the screws are inserted, respectively, into proximal phalanx (13) and intermediate phalanx (14). *Id.*

D. Ground 1: Anticipation of Claim 15 by Slater

Petitioner contends that claim 15 is anticipated by Slater. Pet. 19–32. Petitioner begins with its analysis of independent claim 10 (*id.* at 19–30),

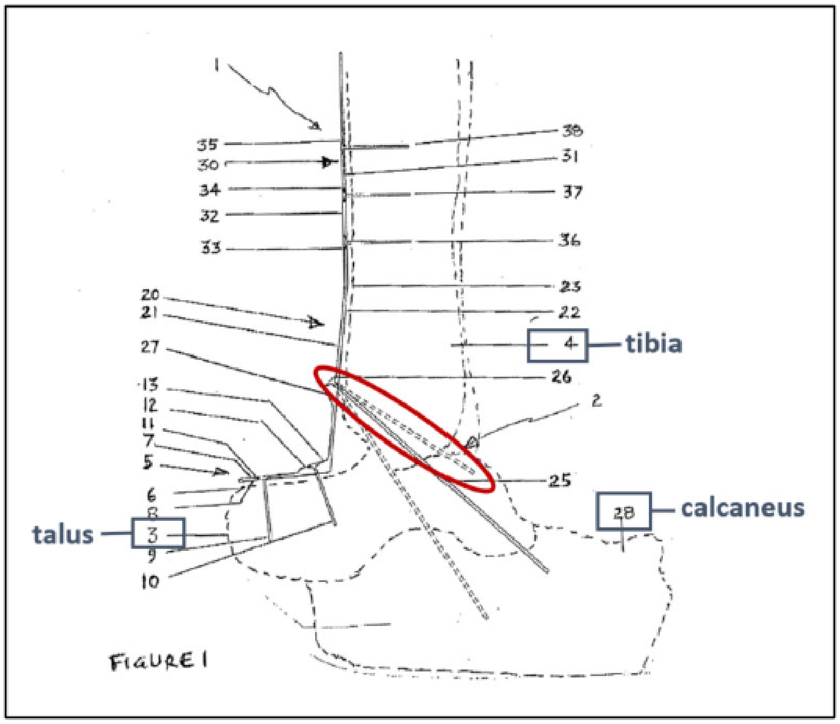
and then addresses the limitations added by dependent claim 15, the sole challenged claim (*id.* at 30–32). Patent Owner raises multiple counterarguments. PO Resp. 23–38.

Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 15 is anticipated by Slater. Our analysis follows.

1. Petitioner's Contentions

Petitioner first contends that, if claim 10's preamble is limiting, Slater discloses a plate for securing two discrete bones together across an intermediate joint between the bones. Pet. 19–20.[1] In support, Petitioner directs our attention to its annotated Figure 1 of Slater, reproduced below, which shows "a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint (dotted lines)." *Id.*; Ex. 1005, 9:28–30.

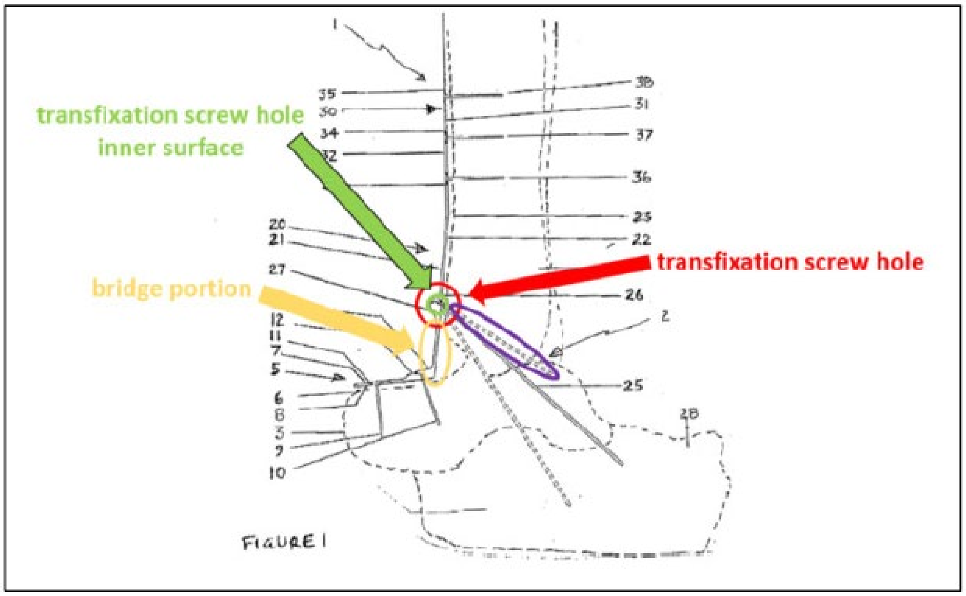
[1] We need not decide whether the preamble is limiting because a system for securing two bones is disclosed in Slater. Moreover, although other portions of claim 10 might limit it to a system for securing two (and only two) bones, it is not apparent at present that the preamble (if it is limiting) excludes a system that secures more than two bones.



Id. Petitioner's annotated version of Figure 1, above, adds boxes and text to identify the tibia, talus, and calcaneus, and also includes a red oval around one of three screw paths shown in the figure. *Id.* Petitioner contends that Figure 1 shows an embodiment where the fusion plate is secured to three discrete bones (tibia, talus, and calcaneus) across two joints between those bones, and also an embodiment where the plate is secured to only two bones (tibia and talus) across one joint between those bones—the latter evidenced by the screw path in the red oval noted above. *Id.* Petitioner supports this interpretation of Slater with Dr. Gall's testimony. Ex. 1002 ¶ 102.

Petitioner further contends that Slater discloses claim 10's elongate spine and first and second ends, as well as a bridge portion between the ends as claimed (labeled by Petitioner as claim limitations 10.1, 10.2, and 10.3). Pet. 20–26 (citing Ex. 1002 ¶¶ 103–109). Petitioner contends that those limitations are disclosed in, for example, Slater's Figure 1 and the features depicted therein. *Id.*

Petitioner also contends that Slater discloses claim 10's recited transfixation screw hole and related functionality, labeled limitation 10.4 by Petitioner. Pet. 26–29. Petitioner cites Slater's Figure 1, with further annotations, as reproduced below.



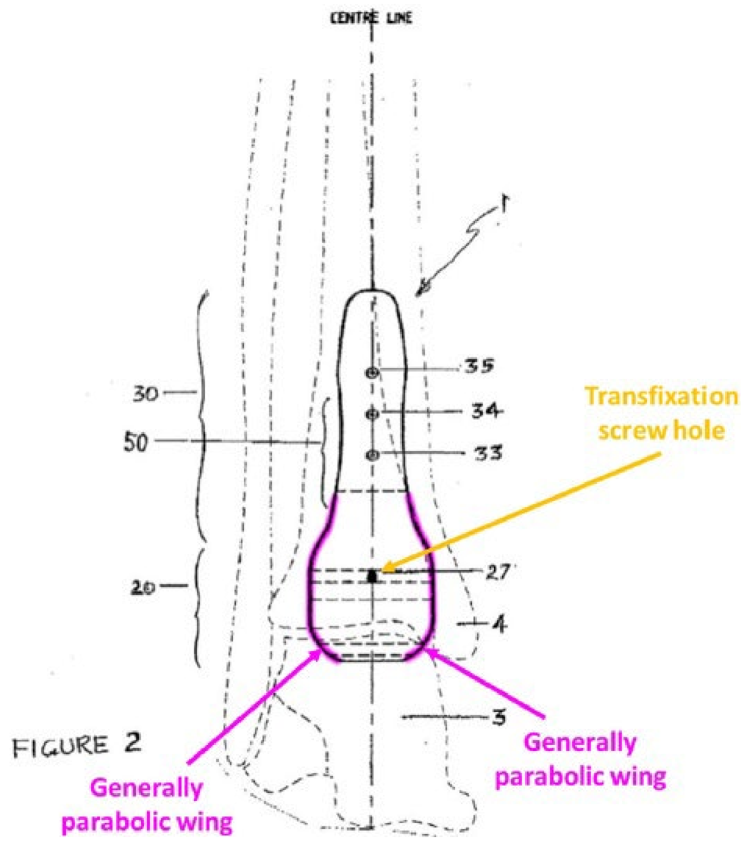
Id. at 26. Petitioner's annotation to Figure 1 identifies transfixation screw hole (with red arrow and circle), inner surface of that screw hole (green arrow and circle), the plate's bridge portion (yellow arrow and oval) and the two-bone screw path discussed above (here, shown inside purple oval). *Id.* (citing Ex. 1002 ¶ 111). According to Petitioner, "Figure 1 shows three separate exemplary angles for transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3)." *Id.* at 27–28; Ex. 1005, Fig. 1.

According to Petitioner, when fixation screw (25) advances through opening (26) into the talus at an angle as shown, the second bone (talus) is loaded relative to the first bone (tibia) and tensile load is transferred from the

talus through the screw into the screw head and plate's bridge portion as claimed. Pet. 28–29. Petitioner explains that "[t]his transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between." *Id.* at 29. Petitioner cites Dr. Gall's testimony to support this understanding of Slater's plate and its functionality when fixed to the tibia and talus as shown. *Id.* (citing Ex. 1002 ¶ 112).

Petitioner next addresses claim 10's recitation of "wherein at least a portion of said bridge portion and said transfixation screw hole has a depth greater than at least a portion of said first and second ends," which Petitioner labels as limitation 10.5. Pet. 29–30. According to Petitioner, a POSA would understand "depth" as meaning "thickness"—a term that appears repeatedly in the patent. *Id.* (citing Ex. 1001, 8:14–33). Petitioner contends that Slater uses the terms depth and thickness interchangeably and otherwise discloses limitation 10.5. *Id.* at 30 (citing, *inter alia*, disclosure in Slater that the plate should have "maximum thickness" at the region where highest loading will occur in normal use); Ex. 1005, 15:19–23; *see also id.* at 8:25–26 (disclosing that portions of the plate at the plate extremity are thinner), 8:32–9:6; Ex. 1002 ¶ 113. With reference to Figures 5 and 7 of Slater, Petitioner contends that Slater discloses limitation 10.5. *Id.* (citing Ex. 1005, Figs. 5, 7; Ex. 1002 ¶ 113). In particular, Petitioner contends that "the first and second ends of the Slater bone plate are tapered[, and a]s such, both the bridge portion and the portions of the plate surrounding the transfixation screw hole are thicker than "at least a portion of" the tapered ends." *Id.* (citing Ex. 1002 ¶ 113; Ex. 1005, 8:25–26, 8:32–9:6, 14:19–23, 24:17–19).

Altogether, Petitioner argues that Slater discloses every limitation of claim 10, and Petitioner then turns to dependent claim 15. *Id.* at 29–32. According to Petitioner, Slater also describes a bone plate with flared hips comprising two generally parabolic wings as claimed (labeled limitations 15.1 and 15.2 by Petitioner). *Id.* Petitioner provides an annotated version of Slater's Figure 2, reproduced below.



Id. at 32. Figure 2, above, is a front elevation view of Slater's plate (the plate as otherwise depicted in a side elevation in Figure 1) and shows the plate oriented for placement on the underlying tibia (4) and talus (3); Petitioner's annotation shows "Generally parabolic wing[s]" (labeled with purple arrows and highlighting) on the lower left and right sides of the plate, extending laterally on opposite sides of the transfixation screw hole (indicated by yellow arrow). *Id.*; Ex. 1002 ¶ 119.

2. Patent Owner's Response

Patent Owner contends that "nothing in *Slater* expressly or inherently discloses transferring the tensile load from the second bone through the fixation screw head and into the bridge portion of the plate." PO Resp. 35. Specifically, Patent Owner contends that Petitioner and Dr. Gall improperly assume that Slater discloses a "vise" configuration to transfer tensile load from the second bone, through the screw and into the bridge portion. *See id.* According to Patent Owner, and its declarant Mr. Sommers, Dr. Gall's assumption depends on the assumption that the threads of Slater's screw 70 would only engage the second bone (the talus) in Slater's two-bone embodiment, but Slater lacks any disclosure to support this assumption. *See id.* at 35–36 (citing Ex. 2002 ¶¶ 106–107; Ex. 2003, 44:21–45:15). Patent Owner argues that Slater does not expressly or inherently disclose Petitioner's "vise" construct, and that Slater fails to disclose how an undisclosed embodiment using the vise approach would transfer tensile load. *Id.* at 36–37 (citing Ex. 1005, 20:14–16; Ex. 2002 ¶ 108). Patent Owner further contends that Dr. Gall's opinion lacks citations of support to Slater, and any reliance on Slater's finite element analysis lacks support because the test data does not state how the transfixation screw was affixed or loaded, or how many bones it penetrated. *Id.* at 37–38 (citing Ex. 1002 ¶ 112; Ex. 2002 ¶¶ 113–115; Ex. 2003, 92:24–93:7).

3. Petitioner's Reply

Petitioner responds that Slater discloses the "vise" configuration because it uses a lag screw "through an angled formation in the bone plate to cross a joint or joints where the screw head is in 'cooperation' with the screw hole," creating a well-known "lag effect" to compress bone parts and

absorb tensile load. Pet. Reply 13–14 (citing Ex. 1002 ¶ 112; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1027 ¶¶ 121–123; Ex. 1028 ¶¶ 33–42; Ex. 1031, 68:17–70:3, 106:19–107:17; Ex. 2003, 46:23–48:4). Petitioner argues that Mr. Sommers conceded that you only want threads in the second bone, and described transfer of tensile load in the '776 patent in the same manner that Dr. Gall describes Slater transfers tensile load. *Id.* at 14–15 (citing Ex. 1002 ¶¶ 112; Ex. 1028 ¶¶ 33–43; Ex. 1031, 74:9–13, 90:24–91:23). Petitioner also argues that "Slater describes in-vivo studies that ***confirm*** tensile load is transferred from the bone to the screw and to the bone plate." *Id.* at 15 (citing Ex. 1005, 17:14–20:26; Ex. 2003, 92:17–93:7; Ex. 1028 ¶¶ 44–45). According to Petitioner, Slater's testing simulated in vivo loading conditions and show that "at least some tensile load is necessarily distributed from the angled screw formation to the bridge portion." *Id.* (citing Ex. 1005, 17:20–21, 19:1–6; Ex. 1028 ¶¶ 45–46; Ex. 1031, 67:23–68:7, 68:18–24, 74:6–25; Ex. 1040).

4. *Analysis*

Independent claim 10 recites

> the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone once the plate is placed across the joint, *enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge*.

Id. at 13:24–14:4 (emphasis added). We will refer to this limitation as the "transfer of tensile load" limitation. The parties dispute whether Slater expressly or inherently disclose this limitation.

We first address Petitioner's argument that Slater discloses a "vise" configuration, which relies on Petitioner's argument that Slater uses a lag

screw with threads on its end that only engage the second bone in Slater's two-bone configuration. *See* Pet. 26–29 (citing Ex. 1002 ¶ 112; Ex. 1005, 11:19–25, 12:32–13:3, 13:21–24); Pet. Reply 13–15 (citing Ex. 1002 ¶ 112; Ex. 1005, 5:28–6:10, 6:18–28, 12:32–13:3, 19:25–26, 22:13–18, 27:11–17; Ex. 1027 ¶¶ 121–123; Ex. 1027 ¶¶ 33–42; Ex. 1031, 67:23–68:7, 68:17–70:3, 70:16–19, 71:5–9, 74:6–25, 75:5–13, 77:14–22, 106:19–107:17; Ex. 2003, 46:23–48:4, 90:24–91:23). We are not persuaded by Petitioner's argument because Slater does not expressly or inherently disclose how its lag screw threads interact with the first and second bone. Slater's Figure 4 "shows an elevation view of a second screw type 70" having "a longer shank to increase depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone." Ex. 1005, 12:32–13:3. This description of screw type 70 in the *three*-bone configuration does not state that the screw *only* engages the third bone, the calcaneus bone, and describes the "majority of the shank" as "slid[ing] through" holes in the first two bones without stating that none of the threads engage a portion of, for example, the end of the second bone adjacent the third bone. *See id.* More importantly, even if this portion of Slater describes a *three*-bone embodiment where the threads only engage the third bone, Slater provides insufficient support for Petitioner's position that the threads of screw type 70 only engage the second bone in Slater's *two*-bone embodiment, which Petitioner relies on as the anticipatory embodiment of Slater. *See* Pet. 27–28; Ex. 1002 ¶¶ 111–112 (arguing that Slater's Figure 1 shows two-bone embodiment). Slater contains no details on this aspect of its alternative two-bone embodiment, such that the threads of the screw may engage the end of

the first bone adjacent the second bone and still provide satisfactory results. At best, Petitioner and Dr. Gall's related testimony establish that it would have been desirable, and perhaps obvious, to have the threads of screw type 70 only engage the second bone in Slater's two-bone embodiment to create a vise-like configuration that transfers tensile load as claimed, but that does not establish that Slater expressly or inherently discloses such an embodiment to satisfy the anticipation standard.

We next address Petitioner's reliance on Slater's finite element analysis tests. *See* Reply 13–15. Petitioner did not rely on this aspect of Slater in the Petition, and raised the argument for the first time in Reply. *Compare* Pet. 28–29, *with* Reply 15. Setting aside the propriety of failing to rely on this aspect of Slater in the Petition, we are not persuaded by Petitioner's argument and evidence for two reasons. First, Petitioner appears to still rely on its argument that Slater discloses a "vise" configuration, and argues that the testing confirms the transfer of tensile load. *See* Reply 13 (relying on "vise" argument), 15 ("Slater describes in-vivo studies that ***confirm*** tensile load is transferred from the bone to the screw and to the bone plate."). Petitioner does not appear to argue that even if we find that Slater does not disclose the "vise" configuration and does not necessarily disclose screw threads that only engage the second bone, that the testing alone shows that Slater discloses the limitation. Reply 15. Accordingly, we do not find the testing argument persuasive due to its link to arguments we find unpersuasive for the reasons discussed above.

Second, Patent Owner correctly points out that Slater provides inadequate information to conclude that the testing results apply to Slater's two-bone configuration such that we can conclude that Slater's two-bone

embodiment results in the claimed transfer of tensile load to the plate's bridge. *See* PO Resp. 37–38 (citing Ex. 1002 ¶ 112; Ex. 2002 ¶¶ 113–115; Ex. 2003, 92:24–93:7). Slater's tests merely simulate the response of its plate to certain loads, and do not purport to show actual loading of the plate on a patient in either the three-bone or two-bone embodiments. Ex. 1005, 17:14–23 (referring to analysis of simulated in-vivo performance and "anticipated loadings" of the plate). Slater also emphasizes that the simulations only apply to "a plate of the particular type and geometry tested" and that "plates with different geometry and dimension . . . may result in different measured loadings and plate response" and "will be likely to have different load capacity results." *Id.* at 20:13–23. Based on the lack of detail as to how Slater's simulations would apply to its two-bone embodiment, and Slater's warning that the simulated results only apply to the specific plate tested, we agree with Patent Owner that Slater's simulated testing does not establish that Slater expressly or inherently discloses the transfer of tensile load limitation in claim 10.

Finally, for similar reasons, we find the testimony of Patent Owner's declarant Mr. Sommers more credible and persuasive than the testimony of Petitioner's declarant Dr. Gall. For example, Dr. Gall opines that Slater discloses a vise configuration, but fails to point to any portion of Slater disclosing that configuration with respect to the two-bone embodiment. *See* Ex. 1002 ¶ 112; Ex. 1027 ¶¶ 37–46. Again, this testimony may establish the desirability of such a configuration and that one of ordinary skill in the art, when using Slater's plate, may do so in the manner Dr. Gall proposes, but that does not establish that Slater expressly or inherently discloses a vise-like configuration due to threaded engagement with only the second bone in

Slater's two-bone embodiment. We view the testimony of Mr. Sommers as more credible because it more accurately tracks Slater's disclosures. *See* Ex. 2002 ¶¶ 57–58 (opining that Slater "does not describe whether there would also be threads" in the second of the three bones in the three-bone embodiment, in practice the threads may engage multiple bones, and Slater does not illustrate or describe how the screw would be used on a two-bone configuration), 81–83, 108–120 (opining that Slater fails to disclose the transfer of tensile load limitations).[2]

Based on the foregoing, we find that Petitioner has not established that Slater expressly or inherently discloses the transfer of tensile load limitations in claim 10 and therefore does not prove, by a preponderance of the evidence, that Slater discloses each element of claim 10. Petitioner's challenge to dependent claim 15 as anticipated by Slater is substantially similar to its analysis of independent claim 10, which relies on Petitioner's predicate analysis on the independent claim. Pet. 30–32. Accordingly, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 15 is anticipated by Slater.

E. Ground 2: Obviousness of Claim 15 over Falkner and Duncan

Petitioner argues that dependent claim 15 would have been obvious over Falkner and Duncan. Pet. 33–48. As with Ground 1, Petitioner begins

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[2] We are also unpersuaded by Petitioner's arguments based on the alleged similarity between the description Mr. Sommers provides of how the '776 patent shows the transfer of tensile load and Dr. Gall's description of how Slater transfers tensile load. *See* Reply 14–15. It is hardly surprising, and largely irrelevant, that Petitioner's declarant would describe the prior art in a manner consistent with the Patent Owner or its declarant's description of the how the challenged patent works. That similarity alone does not establish that the prior art expressly or inherently discloses the limitation in question.

with an analysis of independent claim 10 before moving to the challenged dependent claim 15. *Id.* To support its contention, Petitioner directs our attention to the various disclosures of Falkner and provides a detailed claim analysis addressing how each element of claim 10 is disclosed by Falkner. Pet. 33–43 (citing Ex. 1002 ¶¶ 120–133). Petitioner then directs our attention to the various disclosures of Duncan and provides a detailed claim analysis addressing how each element of claim 15 is disclosed by Duncan, and explains why a person of ordinary skill in the art would have been motivated to modify Faulkner in view of the teachings of Duncan. Pet. 43–48 (citing Ex. 1002 ¶¶ 135–144). Patent Owner raises multiple counterarguments. PO Resp. 39–51.

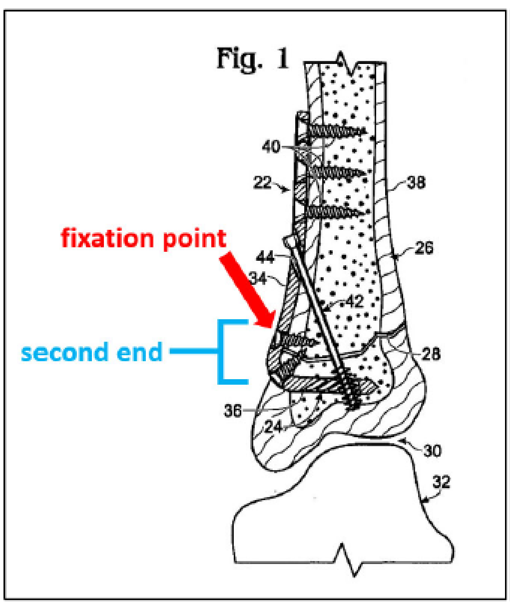
Having considered the parties' positions and evidence of record, we determine that Petitioner has not demonstrated by a preponderance of evidence that claim 15 would have been obvious over Falkner and Duncan. Our analysis follows.

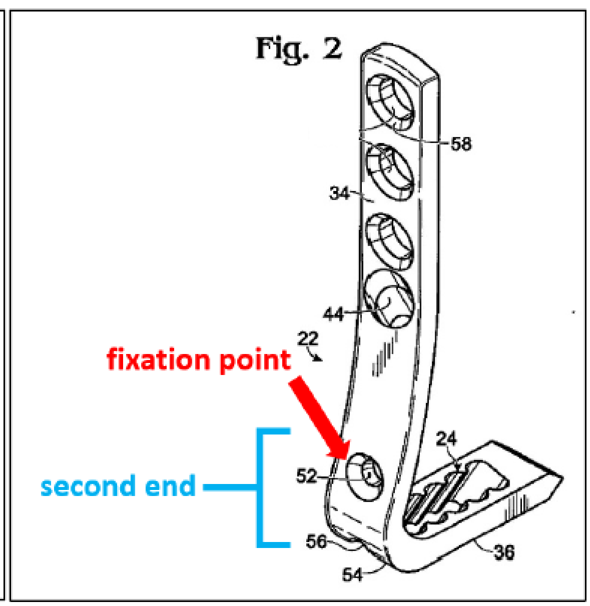
1. Petitioner's Contentions

We begin our analysis with Petitioner's contentions with regard to claim 10. Petitioner contends that Faulkner discloses the preamble and every other element of claim 10. Pet. 33. According to Petitioner, although Falkner's Figure 1 shows a plate for fixing a single fractured bone, Falkner discloses that its bone plates may be used for any suitable "bone(s)" to fix fractures or other bone discontinuities. Ex. 1006 ¶¶ 21, 28. Petitioner cites Falkner's disclosure that, "[i]n other examples, plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." *Id.* ¶ 21 (emphasis omitted).

In a scenario where Falkner's plate spans the ankle joint, Petitioner contends that "plate 22 would be placed across joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22." Pet. 35 (citing Ex. 1002 ¶ 124). And, Petitioner argues, "the inner surface [of the plate] would be configured to substantially conform with a geometry of the first bone (tibia 26)." *Id.* at 35–36 (citing Ex. 1002 ¶ 125; and Ex. 1006 ¶¶ 23, 24 (disclosures in Falkner that one or multiple surfaces of the bone plate may be contoured to follow the exterior surface of a bone or bones, which helps to provide a low profile to the plate)). According to Petitioner, this configuration would meet claim 10's "elongate spine" and "first end" limitations, of element [10.1]. *Id.*

For claim 10's "second end" limitations (labeled element [10'2] by Petitioner), Petitioner cites to Figures 1 and 2 of Falkner (with annotations) as produced below.

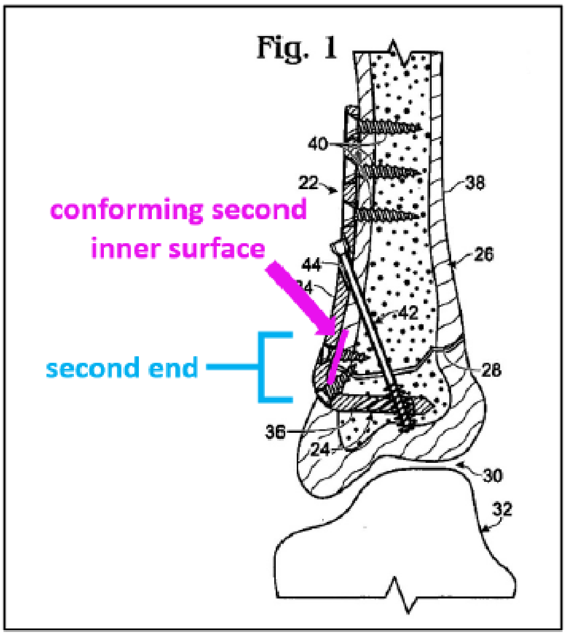




Pet. 36 (citing Ex. 1006, Figs. 1–2). Petitioner's annotated version of Falkner's Figure 1 above shows a cross-sectional view of bone plate 22

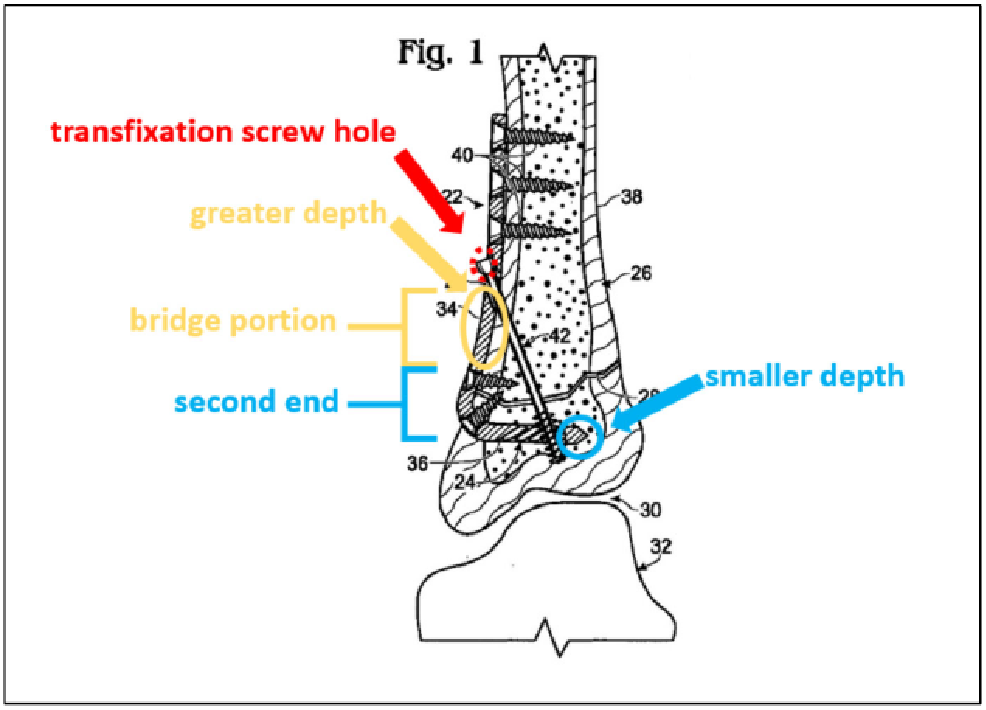
secured to a single bone (tibia, 26), with external plate portion (34) secured to the tibia's external surface and a second (internal) plate portion (36) inserted within the tibia just below fracture (28). *Id.* Petitioner's annotated version of Figure 2 is an isolated perspective view of the same plate further showing the plate's general "L" shape. *Id.* In both figures, Petitioner adds a blue bracket at a segment of external plate portion (36) encompassing a segment at or just above the curve of the L-shaped bracket, which Petitioner names the "second end." *Id.* Petitioner also annotates opening (52) in both figures and, with red arrow and text, names that opening a "fixation point." *Id.*

With that context in mind, Petitioner then argues that, "[i]f the Falkner plate was used to span a joint between tibia 26 and talus 32 . . . a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22." *Id.* at 36–37 (citing Ex. 1002 ¶ 126). And, referencing another annotated version of Figure 1 (reproduced below), Petitioner contends that "the second inner surface would be configured to substantially conform with a geometry of the second bone (talus 32)." *Id.* at 37 (citing Ex. 1002 ¶ 127).



Id. at 37; Ex. 1006, Fig. 1. The version of Figure 1 above is the same cross-sectional view of Falkner's plate attached to the tibia, including Petitioner's blue bracket designating the same alleged "second end," but here, Petitioner annotates (with purple arrow, line, and text) an alleged conforming "second inner surface." Pet. 37. Petitioner's position appears to be that this purple portion depicted in Figure 1 would be adapted and thus configured to conform to the exterior surface of a second bone (the talus) in a scenario where this plate 22 spans, not fracture 28, but joint 30. *Id.*

Turning to claim 10's bridge portion and the requirement that a portion of the bridge and transfixation screw hole have a depth (thickness) greater than a portion of the first or second ends (elements 10.3 and 10.5), Petitioner provides another annotation to Falkner's Figure 1. *Id.* at 38, 40–42. This annotated figure is reproduced below.



Id. at 42; Ex. 1006, Fig. 1. This annotated version of Figure 1 of Falkner, above, shows the same plate attached to the tibia. Petitioner designates another segment of Falkner's exterior plate portion (34) as being a "bridge portion," which Petitioner marks with a yellow oval, bracketing, and text. Pet. 42. Petitioner also indicates (with yellow arrow and text) that this alleged "bridge portion" has a "greater depth." *Id.* This alleged bridge portion or section is immediately above the blue-bracketed "second end" as discussed above. Here, however, Petitioner identifies a tip of internal plate portion (36) (i.e., the portion of the plate inserted within the tibia) as having a "smaller depth," which Petitioner highlights with a blue circle, arrow, and text. *Id.* This annotation also identifies the alleged transfixation screw hole, which Petitioner highlights with red text, arrow, and hashed circle. *Id.*

Petitioner argues that, "[a]s can be seen in Figure 1, at least a portion of the bridge portion and the transfixation screw hole (44) has a depth or thickness greater than at least a portion of said first and second ends." *Id.* at

41–42. According to Petitioner, the alleged "second end" is "thinner at the end" to aid insertion into the bone and becomes thicker toward the bridge to add stability. *Id.* (citing Ex. 1006 ¶ 35).

For the transfixation screw hole and transfixation screw limitations of element 10.4, Petitioner identifies Falkner's Figures 1 and 2. As shown in those figures, Petitioner cites Falkner's oblique opening (44) in external plate portion (34), and threaded fastener (42) configured for insertion into said opening and fixed engagement with toothed aperture (24) on the plate's internal plate portion (36). Pet. 39–40. According to Petitioner, Falkner's oblique opening is a "transfixation screw hole" as claimed, and, in a configuration where Falkner's plate is designed to attach to a tibia and talus, spanning the joint between those bones, the fastener (i.e., screw) would extend through a portion of tibia (26), through joint (30), and into a second discrete bone (talus, 32). *Id.* And, in that configuration, Petitioner contends the talus is loaded relative to the tibia and tensile load is transferred from the talus through the screw and into the bridge portion. *Id.* at 40 (citing Ex. 1002 ¶ 132). In support, Petitioner cites Falkner's teaching that "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." Pet. 40 (quoting Ex. 1006 ¶ 71).

Having cited disclosure in Falkner that allegedly meets all the limitations of claim 10, Petitioner moves to claim 15 and the recited "flared hip[s]." *Id.* at 43–48. Petitioner cites Duncan's Figure 2, reproduced below with Petitioner's annotations, as teaching the flared hips comprising generally parabolic wings as recited in claim 15.

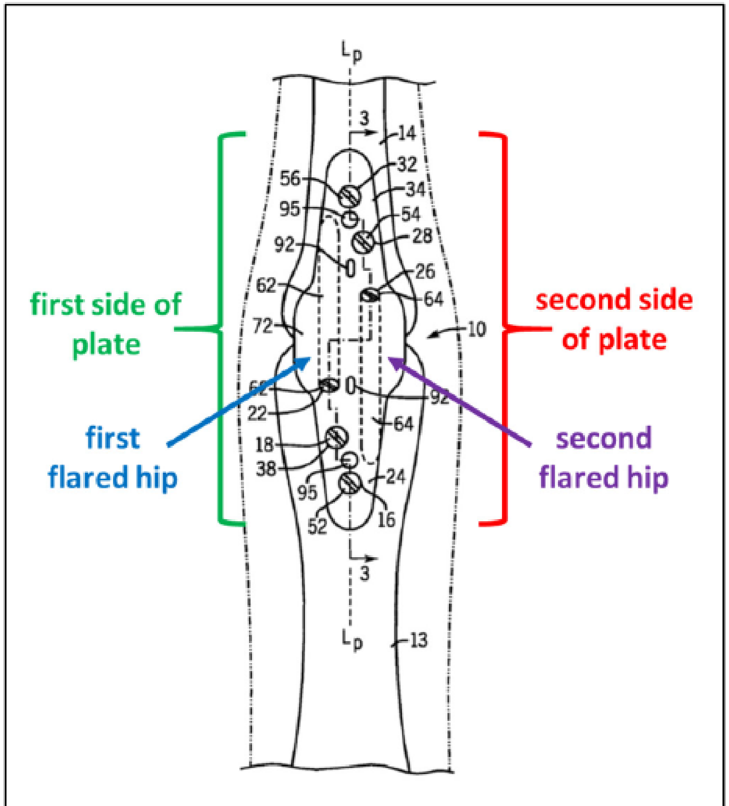


FIG. 2

Id. at 44 (citing Ex. 1016, Fig. 2). Duncan's Figure 2, above, depicts a bone plate (10) attached to two bones (13 and 14) of a finger; Petitioner's annotation highlights the alleged first and second sides of the plate with, respectively, green and red brackets. *Id.* at 44–45. Petitioner identifies, with blue and purple arrows, the alleged first and second flared hips of the plate on the respective first and second sides of the plate. *Id.* (citing Ex. 1002 ¶¶ 140–144 (testimony that the hips are symmetrically opposed as parabolic wings)).

Petitioner contends it would have been obvious to modify Falkner's plate to include the symmetrically flared hips of Duncan. *Id.* at 46–48. According to Petitioner, a POSA would understand that bone plates can be strengthened by making certain portions thicker and wider to counteract

higher stress that occurs in those portions. *Id.* (citing Ex. 1002 ¶ 142–143). Petitioner alleges that a POSA would understand that including an angled screw hole, such as Falkner's oblique opening (44), results in more plate material being hollowed out such that the plate may require additional strength in those areas. *Id.* at 46 (Ex. 1002 ¶ 141). Petitioner argues that, in addition to thickening the area around the angled screw hole, a POSA would understand that widening the plate around the screw hole will provide added support, and that the need for such support would have motivated a POSA to include flared hips on the plate, such as disclosed in Duncan, particularly if Falkner's plate is designed for use on the medial side of the ankle. *Id.* at 46–47 (citing Ex. 1002 ¶¶ 142–143). Petitioner further contends that a parabolic shape to the hips around the screw hole would help surgeons properly position the plate over the joint. *Id.* at 47 (citing Ex. 1002 ¶ 144). Petitioner argues these changes would have been made with a reasonable expectation of success, predictably adding strength to the plate and adding visual cues to help position the strongest part of the plate over the joint. *Id.*

2. Patent Owner's Response

Patent Owner raise multiple counterarguments to Petitioner's Ground 2 and challenges Petitioner's reasoning for combining Falkner and Duncan. *See* generally PO Resp. 39–51.

First, Patent Owner argues that Ground 2 is treated as an "anticipation analysis" with respect to the underlying analysis of independent claim 10 from which challenged claim 15 depends. *Id.* at 39 n.4. But, according to Patent Owner, Falkner "fails to disclose each and every element of [claim 10], arranged as in the claim." *Id.*

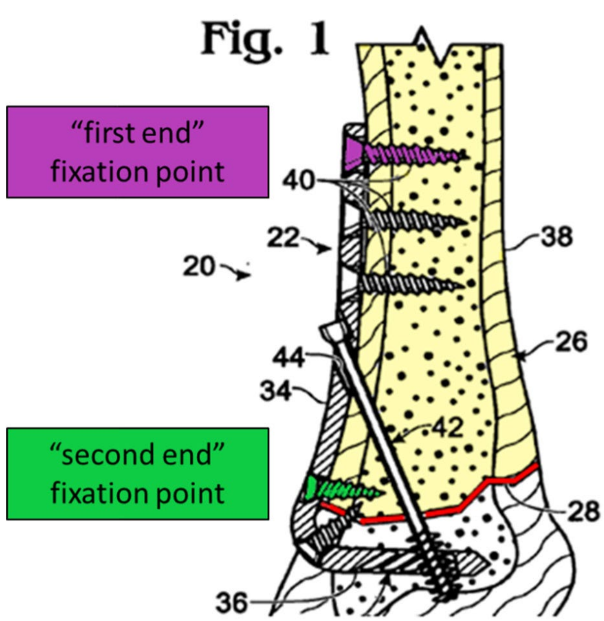
Second, Patent Owner argues that "*Falkner's* plate is not designed to secure 'two discrete bones together across an intermediate joint,'" as seen in "Figure 1 itself, which shows a blade-plate solely on the tibia bone with the talus bone untouched." PO Resp.40 (citing Ex. 2002 ¶ 120). According to Patent Owner, although "*Falkner* explains that this type of blade-plate may be configured to cross a joint rather than a bone fracture, *Falkner* includes 'a dearth of detail about such a hypothetical plate's design.'" *Id.* (citing Paper 10, 39; Ex. 2002 ¶ 121). Patent Owner contends that Falkner does not disclose a single embodiment that meets all the limitations of claim 10, so Petitioner and Dr. Gall's testimony "far exceeds what is described in the 'four corners of that document [] either expressly or inherently,'" to stretch Falkner's single-bone embodiment to explain how Falkner's plate would have been configured in a different context to reach the claimed subject matter. *Id.* at 42.

Next, Patent Owner argues that Falkner fails to disclose a "second end" that includes a "fixation point" and an "inner surface configured to substantially conform with a geometry of the second bone" as required by claim 10. *Id.* at 42–46. Patent Owner argues that what Petitioner identifies as the "second end" of Falkner's plate is inside the bone and therefore does not conform to the geometry of the second bone. *Id.* at 44. Patent Owner further contends that:

> With the interior portion of the Falkner blade-plate unable to conform to the geometry of the second discrete bone, the Petition relies on Dr. Gall, rather than the disclosure of Falkner, to conclude that "the plate 22 ***would have been*** placed across the joint 30 and the second inner surface ***would have been*** configured to substantially conform with a geometry of the second discrete bone (talus 32)." (Ex. 1002, ¶ 178 (emphasis added)). That something "would have been configured" is the

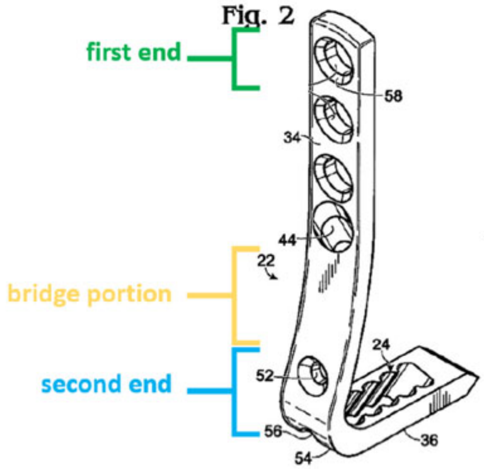
> hallmark of obviousness, and perhaps recognizing this after the fact, Dr. Gall at his deposition seemingly changed course and indicated that a Falkner plate spanning a joint would still include the portion that is interior to the bone. (Ex. 2003, 86:11–15). Therefore, Falkner fails to disclose a second end configured to "substantially conform with a geometry of the second discrete bone."

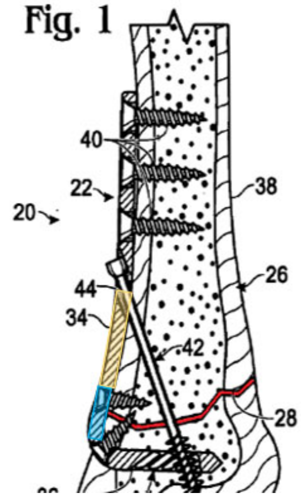
PO Resp. 44–45. Patent Owner asserts that although Petitioner also identifies another portion of the blade-plate as the "second end," Petitioner's "identified fixation point is not on the second bone (or on the second part of the fractured bone) at all." *Id.* at 45 (citing Ex. 2002 ¶¶124–125). According to Patent Owner, "Petitioners rely upon a second end fixation point (green) that is on the **<u>same side</u>** of the bone discontinuity as the first end fixation point (purple), as shown in the annotated image below. *Id.* (citing Ex. 2002 ¶ 125).



PO Resp. 46 (citing Ex. 1006, Fig. 1). Falkner's Figure 1, above, depicts a bone plate 22 attached to tibia 26; Patent Owner's annotation highlights the alleged first and second fixation points with, respectively, purple and green screws with correspondingly colored label boxes adjacent the screws. *Id.* Patent Owner asserts "[i]f the *Falkner* blade-plate were modified to span a joint rather than a fracture, a POSITA would try to position the plate such that the joint would be in the same location as the fracture shown in Figure 1 to preserve the design intent of the *Falkner* concept." *Id.* (citing Ex. 2002 ¶ 126). Thus, according to Patent Owner, even under this additional "second end" of Falkner, "Falkner fails to meet the "second end" limitations of claim 10. *Id.* (citing Ex. 2002 ¶ 127).

Lastly, Patent Owner contends that Petitioner's modified version of Falkner's plate does not have any portion configured to span across the bridge portion. PO Resp. 47–49. Patent Owner explains that even if the Falkner plate can be moved across the joint, the plate would cross the "second end", not the bridge portion. *See id.* at 47 ("the *Falkner* blade-plate 'bridge portion' that Petitioners rely upon would not cross the joint at all"). To illustrate that point, Patent Owner references and compares Dr. Gall's annotated image of Falkner's figure 1, shown below on the left, and Mr. Sommers annotated image of Falkner's figure 2, shown below on the right.





Id. at 47 (citing Ex. 1006 Fig. 1 (Dr. Gall's annotations from Ex. 1002 ¶ 115); Ex. 2002 ¶ 137 (depicting Ex. 1006, Fig. 2 (annotated))). Figure 1 is a sectional view of a bone plate according to Falkner as in would be applied to a bone. Ex. 1001 ¶ 8. Figure 2 is a perspective view of a bone plate according to Falkner in the absence of fasteners and bone. *Id.* ¶¶ 9, 67. Patent Owner contends that the figures show that Falkner's plate would cross the joint at the portion of the plate Petitioners identify as the "second end." PO Resp. 47. Patent Owner further explains that, "[a]s can be seen from Mr. Sommers' modified version of Figure 1, the bone discontinuity shown in red actually intersects the second end Dr. Gall has identified, highlighted in blue, just below the second end fixation point Dr. Gall relies upon, not his bridge portion shown in yellow." *Id.* at 48 (citing Ex. 2002 ¶ 138). Thus, according to Patent Owner, the Falkner plate does not cross the bone discontinuity in Figure 1.

3. Petitioner's Reply

In its Reply, Petitioner responds that "Falkner unambiguously teaches that ***the same bone plate*** shown in Figure 1 and described in the [S]pecification 'may be positioned on and/or in any suitable bone(s) to span

any natural or artificial discontinuity within a bone or between bones.'" Reply 17 (citing Ex. 1006 ¶¶ 21, 28–29, 33–34, 62). Petitioner cites to a new expert, Dr. Holmes, in support of its position. Ex. 1029. Petitioner argues that extensive modifications to the Falkner plate would not be required and refers to Dr. Holmes' testimony who believes that "Falkner enables a POSITA to use its plate for joint fusion ***without any design modifications***." Reply 17–18 (citing Ex. 1028, ¶¶ 19–20, 25–36). Instead, Petitioner cites to Dr. Holmes who describes a procedure whereby:

> [S]urgeons typically shave straight (transversely) across the distal surface of the tibia to create a flat surface to oppose with the flat surface of the dorsal surface of the talus" to help create a biomechanically stable joint for fusion. (Ex.1029, ¶¶31-32). The bones are then positioned to create the optimal biomechanical alignment for proper gait following the fusion. (*Id.*, ¶33). The Falkner plate would be positioned to span the joint in the range between the angled screw hole and the internal blade to optimize purchase and efficacy. (*Id.*, ¶35). Depending on patient anatomy, the plate could be contoured with plate benders. (*Id.*, ¶34).

Reply 18. Petitioner contends that Falkner "expressly enables a [person of ordinary skill in the art] to use its bone plate for joint fusion, and teaches all of the ***structural*** limitations set forth in the challenged claims." *Id.* at 19.

4. Patent Owner's Sur-reply

In its Sur-reply, Patent Owner responds that Falkner does not disclose the modifications required to anticipate the challenged claim and instead, Petitioner relied heavily on Dr. Holmes' testimony on how the plate could have been modified. Sur-reply 11. Patent Owner also contends that the modifications to Falkner described in Dr. Holmes' testimony amount to more than slight modifications, and "seemingly admit[s] that *Falkner's* passing reference to a two-bone embodiment is insufficient to anticipate

Claim 10 and insufficient to render the [Claim 15] obvious in view of *Falkner* and *Duncan*." *Id.* at 16–17 (citing, Inst. Dec., 38–39). Patent Owner then explains the various ways in which the modifications of the Falkner plate by Dr. Holmes fail. *See* Sur-reply 16–20 ("the extensive modifications required for Falkner's plate to be used across a joint go beyond what reasonably could be anticipation").

5. Analysis

Having considered the parties' positions and evidence of record, summarized above, we determine that Patent Owner has the better position. Petitioner's position does not prevail for at least the reasons set forth on pages 39–49 of the Patent Owner Response and pages 16–20 of the Sur-reply, which we adopt. In particular, we agree with Patent Owner that Falkner's relied-upon plate shown in Figure 1 is not arranged as claimed. PO Resp. 40–41; Ex. 1006, Fig. 1. It is *not* configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured as claimed would apparently require at least some level of redesign or modification. Yet, Petitioner cites to its filing in related IPR2021-01451 as allegedly supporting its challenge here. Pet. 33 ("As an initial matter and as shown below, in the accompanying Declaration, and in earlier-filed IPR2021-1451, *Falkner discloses every element of Claim 10 of the 776 patent*") (emphasis added).

Moreover, to the extent Petitioner's challenge purports to modify Falkner's single-bone embodiment (e.g., as shown in Figures 1 and 2) by citing various other teachings in Falkner, we see minimal analysis that explains why the POSA would have been motivated to make those modifications with a reasonable expectation of success to arrive at claim 10's subject matter. Even when only one reference is involved, the mere fact that each claim limitation might be found in such reference's disclosure does not necessarily prove obviousness without analysis that explains why the skilled artisan would have combined those teachings to arrive at the claimed subject matter. *In re Stepan Co.*, 868 F.3d 1342, 1345–46 n.1 (Fed. Cir. 2017) ("Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, *there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful*, otherwise a skilled artisan would not arrive at the claimed combination.") (emphasis added). Falkner's cited plate in Figures 1 and 2 is not arranged as claimed. Ex. 1006, Fig. 1. It is not configured to secure two discrete bones (e.g., the tibia and talus) across an intermediate joint between those bones, nor is the plate configured with first and second ends having inner surfaces that substantially conform with a geometry of first and second discrete bones. This is plain from the cross-sectional anatomical views of the tibia, joint, and talus shown in the figure itself. To make the plate so configured would seemingly require redesign or modifications. Petitioner's obviousness analysis on claim 10 is, however, wanting for detail as noted above (e.g.,

minimal explanation why the POSA would have modified the Falkner plate with a reasonable expectation of success).

We recognize that Falkner discloses that its plates may be designed to traverse a joint between bones, including the ankle joint. *See, e.g.*, Ex. 1006 ¶¶ 21, 23, 29. But there is a dearth of detail about such a hypothetical plate's actual design. On this record, it appears to us that making such a plate or modifying the plate of Figure 1 to render it suitable to, for example, spanning a joint between the tibia and talus would require the person of ordinary skill in the art to make distinct design choices beyond any embodiment explicitly described in Falkner. Even then, it is not a foregone conclusion that all the claim limitations would be met (e.g., surfaces of the first and second ends that conform to a bone geometry, and a thicker bridge and screw hole portion relative to the ends), and Petitioner provides minimal argument and evidentiary support to explain why all the claimed features would be included. Petitioner argues, for example, that Falkner's Figure 1 shows a portion of a transfixation screw hole that has a depth greater than a portion of the plate's first and second ends. Pet. 40–42. What Petitioner identifies, however, is not the screw hole but the head of a screw. *Id.* at 42 (hashed red-circle). Neither the identified bridge portion nor screw hole itself appears to have a depth greater than the plate's first end—claim 10 recites that the depth be greater than a portion of the *first **and** second ends*. Petitioner briefly remarks that Falkner "contemplates reducing the [plate] thickness of the bone plate to minimize irritation of soft tissue in regions such as the 'first end' of the plate." *Id.* at 41 (citing Ex. 1006 ¶¶ 32, 35; Ex. 1002 ¶ 133). But, on this record, whether Falkner's cited disclosures teach or suggest that the plate's first end, in particular, should be made

thinner than the bridge and screw hole portions lacks clarity; and Petitioner does very little to explain why a POSA would have been motivated to decrease the thickness at that specific part of the plate.

Moreover, we note that Petitioner, in one instance and attempting to show satisfaction of one claim limitation, cites a portion of Falkner's plate that appears to be close to the middle of the plate and characterizes that portion as a "second end." Pet. 41–42. Yet, when wanting to show that the second end of the plate is thinner than the bridge, Petitioner points to another portion of the plate—the distal-most tip of the plate, which is actually inserted in the bone itself. *Id.* Petitioner's position on what constitutes the "second end" of Falkner lacks a degree of clarity and consistency. Petitioner may be cherry-picking certain features of a single-bone embodiment to keep, which features it sees as favorable to its position, while purporting to modify other portions of that embodiment (e.g., contouring the plate to a particular bony geometry) in order to render it suitable for a different attachment across multiple bones. As noted above, however, Petitioner's arguments lack explanation as to why the POSA would have modified the Falkner plate with a reasonable expectation of success.

Petitioner relies on Duncan principally for its teaching related to the "flared hips" feature (elements 15.1/15.2) of the challenged claim. *Id.* at 45–48. Petitioner's reliance on Duncan and reasoning for adding the flared hips, does not remedy the concerns noted above with Petitioner's showing on the subject matter recited in claim 10.

Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claim 15 would have been obvious over Falkner and Duncan.

III. CONCLUSION

In summary:

Claim	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
15	102	Slater		15
15	103	Falkner, Duncan		15
Overall Outcome				15

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claim 15 of the ’776 patent is not determined to be unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.